TO STUDY THE OUTCOME OF TYPE 2 DIABETES MELLITUS IN PATIENTS UNDERGOING MINI GASTRIC BYPASS USING DIABETES REMISSION SCORE CALCULATOR

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I hereby declare that the thesis entitled "**TO STUDY THE OUTCOME OF TYPE 2 DIABETES MELLITUS IN PATIENTS UNDERGOING MINI GASTRIC BYPASS USING DIABETES REMISSION SCORE CALCULATOR**" submitted towards partial fulfillment of the requirements for the award of **MS in GENERAL SURGERY** degree to BFUHS is a compilation of original work carried out by me under the supervision of Dr. Prabhdeep Singh Nain, Professor, Department of Surgery, Dr. Parminder Singh, Professor & Head, Department of Endocrinology and Dr Ashish Ahuja, Professor, Department of Surgery. No part of this thesis has formed the basis for the award of any degree previously.

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Dedicated

to

my Family

&

Teachers

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Dr. Shubhankar Matta

LIST OF ABBREVIATIONS

ACC	American college of cardiology
ADA	American diabetes association
AHA	American heart association
BMI	Body mass index
BPD	Biliopancreatic diversion
CCK	Cholecystokinin
CI	Confidence interval
DRS	Diabetes remission score
DS	Duodenal switch
DSG	Diverted sleeve gastrectomy
FBS	Fasting blood sugar
FG	Fasting glucose
GIP	Glucose dependent insulinotropic peptide
GJ	Gastrojejunostomy
GLP 1	Glucagon like peptide 1
GTT	Glucose tolerance test
HbA1c	Glycosylated haemoglobin
IC	Ileocaecal
LAGB	Laparoscopic adjustable gastric banding
LDL	Low density lipoprotein
LMGB	Laparoscopic mini gastric bypass
LRYGB	Laparoscopic roux en Y gastric bypass
LSG	Laparscopic sleeve gastrectomy
NIDDM	Non insulin dependent diabetes mellitus
OHA	Oral hypoglycaemic agents
RYGB	Roux en Y gastric bypass
SBP	Systolic blood pressure
SD	Standard deviation
SG	Sleeve gastrectomy
T2DM	Type 2 diabetes mellitus
T2D	Type 2 diabetes
VBG	Vertical band gastroplasty
WHO	World health organisation
%EWL	Percentage excess weight loss
%WL	Percentage weight loss

ABSTRACT

Background: Bariatric surgery has evolved from a surgical measure for treating morbid obesity to an epochal remedy for treating metabolic syndrome as a whole, which is represented by type 2 diabetes mellitus. The present study was conducted to determine the outcome of type 2 diabetes mellitus in patients undergoing mini gastric bypass using the Diabetes Remission Score Calculator.

Methodology: A total number of 24 morbidly obese diabetic patients with BMI >35 kg/m2, who underwent mini gastric bypass, were selected for this study. An analysis of the diabetes remission scoring systems was applied to these patients and its predictive abilities were analyzed.

Results: Mini gastric bypass resulted in significant reduction in weight, BMI, FBS, HBA1c, OHA dose and insulin dose at 6 months. Complete remission of diabetes occurred in 58.3% of patients at 6 months. It was noted that, DRS score of ≤ 8 had the maximum AUC of 0.98 and best sensitivity and specificity to predict the remission of T2DM, i.e., 100% and 66.7%.

Conclusion: Mini gastric bypass leads to the substantial weight loss and amelioration of type 2 diabetes. Diabetes remission score is a useful tool for predicting the remission in patients with type 2 diabetes undergoing mini gastric bypass. We propose DRS as a simple tool to predict the postoperative diabetes remission. Further multicenter studies of patients from various ethnicities are required to confirm our preliminary observations.

Keywords: diabetes, obesity, BMI, bariatric surgery, mini gastric bypass, DRS, diabetes remission

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INTRODUCTION

In 2010, overweight and obesity were estimated to cause 3·4 million deaths, 3·9% of years of life lost, and 3·8% of disability-adjusted life-years (DALYs) worldwide. The rise in obesity has led to widespread calls for regular monitoring of changes in overweight and obesity prevalence in all populations. Comparable, up-to-date information about levels and trends is essential to quantify population health effects and to prompt decision makers to prioritise action.[1]

Economic development in India has led to a shift in disease burden, with a huge increase in non-communicable disease. The prevalence of obesity, for example, has risen even in rural areas. Some 42% of the population in rural Kerala have been reported to be either overweight or obese.[2] A study of an urban slum in northern India reported 40% of the women to be obese,[3] and the prevalence of obesity among 350 patients attending a clinic for diabetes mellitus in Gujarat was 70%.[4]

Obesity is the accumulation of adipose tissue to excess and to an extent that impairs both physical and psychosocial health and well-being. The prevalence of obesity in Western and westernizing countries has doubled over the past decade, with 20% of males and 25% of females now classified as obese in the United States.

It is possible to measure body fat directly; but, although accurate, these methods are expensive, time-consuming, and unsuited to fieldwork and most clinical work. Body mass index (BMI), defined as {weight (kg)/height $(m)^2$}, is the accepted measure of obesity in populations and in clinical practice. A height-independent measure of weight, BMI is a robust but indirect measure of body fatness that provides more reliable results than “ideal weight” estimations or other ratios of weight to height. BMI is the most commonly used tool to define obesity.[5]

TABLE 1: WHO CLASSIFICATION OF OBESITY

Class	BMI
Underweight	< 18.5
Normal range	18.5 – 24.9
Overweight	25 – 29.9
Obese class 1	30 – 34.9
Obese class 2	35 – 39.9
Obese class 3	>40

A study was conducted by Kevin R Fontaine et al. in 2013 in which it was estimated that total life expectancy of a severely obese male (BMI >45) would be 13 years less than a non obese individual and that of a severly obese female would be 8 years less. For men, this would mean a 22% reduction in life span.[6]

MECHANISM OF OBESITY

Adipose tissue is an endocrine organ made up of adipocytes, various stromal cells including many immune cells, and an endothelial network. Adipose secretory products, collectively referred to as adipokines, have been identified as contributors to the negative consequences of adipose tissue expansion including cardiovascular disease, diabetes, and cancer. Systemic circulation provides transport capabilities for adipokines and fuels for proper adipose tissue function. The adipose tissue microcirculation is heavily impacted by adipose tissue expansion. A subset of adipokines can induce endothelial dysfunction. Furthermore, angiogenesis is necessary to counter hypoxia arising as a result of tissue expansion. Tumors, such as invasive lesions in the mammary gland, co-opt the adipose tissue microvasculature for local growth and metastatic growth and lymphatic circulation provides an important route for lipid transport.[7]

Adipose tissue develops in several distinct anatomical depots within the body, and the differential expansion of these depots is of great importance. Expansion of visceral or abdominal white adipose tissue (WAT) has been most strongly correlated to insulin resistance and cardiovascular disease in humans and animals.[8] Conversely,

expansion of subcutaneous WAT does not appear to have the same negative systemic consequences on metabolism.[9] At the other end of the spectrum is the condition of lipodystrophy wherein the dramatic loss of adipose tissue triggers a high degree of insulin resistance and signs of other metabolic dysregulation similar to visceral WAT expansion. The importance of maintaining at least remnants of WAT was demonstrated by injecting adipocyte progenitors into the residual adipose depots lipodystrophic mice: the depots expanded and the systemic metabolic profile was properly restored.[10] Brown adipose tissue (BAT) is in an entirely different metabolic category due to its primary function in generating body heat in infants and rodents. BAT is rich in mitochondria, highly vascularized, and because it affords none of the ill effects of visceral WAT, serves as an ideal paradigm for “good” adipose, despite its limited presence in adult humans.[11]

Many theories have been proposed explaining the mechanism of obesity. The theory of metabolic thrift explains the polymorphisms that cause propensity towards weight gain got selected during evolution as opposed to those causing weight loss getting rejected. Many studies show that there are numerous genetic factors that may cause a tendency towards weight gain. Another theory explains that maternal nutritional extremes during gestational period may cause epigenetic changes to occur in the fetus that favor obesity, insulin resistance and metabolic diseases.[12]

Bariatric surgery is seen as a tool for tackling obesity. Some studies suggest that bariatric surgery could even help to prevent diabetes mellitus.[13]

Patients with diabetes often find it difficult to cope with multiple insulin injections. They can feel frustrated when their glycaemic control remains poor despite their best efforts. Their quality of life can decline,[14] and a vicious cycle of non-adherence to treatment and poor glycaemic control can set in. The quality of life of obese patients undergoing bariatric surgery is thought to improve as a result of weight loss and many patients perceive bariatric surgery to be a panacea.[15]

The number of patients in India undergoing bariatric surgery is rising. The Obesity Surgery Society of India has stated that the number of people having such surgery rose from 2200 in 2010 to more than 5000 in 2011.[16]

Bariatric surgery has evolved from a surgical measure for treating morbid obesity to an epochal remedy for treating metabolic syndrome as a whole, which is represented by type 2 diabetes mellitus. Numerous clinical trials have advocated bariatric or metabolic surgery over nonsurgical interventions because of markedly superior metabolic outcomes in morbidly obese patients who satisfy traditional criteria for bariatric surgery (body mass index [BMI] >35 kg/m^2) and in less obese or simply overweight patients.[17]

The indications to undergo bariatric surgery, are based on body mass index (BMI) as well as the presence of comorbidity. Patients with a BMI of 40 kg/m2 or greater without coexisting medical problems, and for whom bariatric surgery would not carry an excessive risk, should be candidates for bariatric surgery.

Patients with a BMI greater than or equal to 35 kg/m2 and 1 or more severe obesity-related comorbidities, including type 2 diabetes, hypertension, hyperlipidemia, obstructive sleep apnea (OSA), non-alcoholic fatty liver disease (NAFLD), GERD, asthma, venous stasis disease, severe urinary incontinence, debilitating arthritis, or considerably impaired quality of life, would also qualify as surgical candidates. Patients with BMI OF 30 to 34.9 kg/m2 with diabetes or metabolic syndrome also may undergo weight loss surgery.[18]

There are various types of bariatric surgeries:

1. Purely restrictive
    - Laparoscopic adjustable gastric banding
    - Vertical banded gastroplasty
    - Laparoscopic sleeve gastrectomy
2. Largely
    - Biliopancreatic diversion (BPD malabsorptive, mildly restrictive) with or without a duodenal switch

3. Largely restrictive, moderately malabsorptive
    - Laparoscopic mini gastric bypass
    - Laparoscopic Roux-en-Y gastric bypass

Mini gastric bypass was first performed by Robert Rutledge in 1997 in the era of open bariatric surgery and the dawn of minimally invasive surgery. The operation is based on sound general surgical principles combining a “non-obstructive” Collis Gastroplasty, which is an esophageal lengthening procedure with a Billroth II ante-colic Loop gastro-jejunostomy. Mini-Gastric Bypass (MGB) is becoming more and more popular as shown by the numerous articles published over the past 15 years, supporting the operation as a short and simple procedure with excellent outcomes and low complication rate. The MGB consists of a long conduit from below the crow's foot extending up to the left of the angle of His. It is similar to, but importantly, not the same as the pouch of the Sleeve Gastrectomy. MGB has a wide gastro-jejunal anastomosis to an anti-colic loop of jejunum 150–200 cm distal to the ligament of Trietz. The power of MGB comes from the fact that it is both a “Non-Obstructive” restrictive procedure and it also has a significant fatty food intolerance component with minimal malabsorption. Mini-Gastric Bypass has been shown to be a valuable addition to the armamentarium of bariatric surgery. Its popularity is increasing around the world. MGB has been shown to be a simple, low risk and effective weight loss surgery which has a durable weight loss with a high level of patient satisfaction. It has few advantages that it has a short learning curve and is simple to reverse or revise.[19]

Bariatric surgery has proved to be a useful tool in control/remission of type 2 diabetes mellitus. American heart association/ American college of cardiology guidelines recommend conservative therapy for those with BMI >30 or BMI between 25-29.99 with obesity related comorbidities. They recommend bariatric surgery for those with BMI greater than 40kg/m^2 or a BMI greater than 35kb/m^2 with an associated comorbid medical problem and failure to achieve weight loss by dietary and behavioral therapy.[20]

Various studies have been conducted to determine predictors of remission of Type 2 Diabetes Mellitus after bariatric surgery. Some key parameters that have been studied are age, BMI, fasting blood glucose, HbA1c, duration of T2DM, C-peptide levels.

Several scoring systems have been developed to predict the outcome of diabetes post bariatric surgery. Out of all these, the Diabetes Remission Score (DRS) Calculator shows much promise.

The Diabetes Remission Score (DRS) was proposed by Surendra Ugale et al. in their retrospective cohort study conducted using records of patients from 2008 to 2010 at a hospital in Hyderabad, Telangana. The unique feature of this scoring system was the inclusion of pre operative insulin use and presence of macro and micro vascular complications criteria in addition to previously studied factors like age, BMI, duration of T2DM, C-peptide.[21]

Mini gastric bypass is becoming more and more popular, especially in India, and has proven to be a safe and effective alternative to other bariatric procedures with less morbidity and post op complications. Not many studies have been conducted to evaluate the outcome of diabetes after Mini gastric bypass. This study aims to predict the outcome of remission of T2DM after Mini Gastric Bypass using a relatively newer scoring system (DRS). Other scoring systems have been used to study the outcome of diabetes post bariatric surgery such as the ABCD scoring system and the DiaRem scoring system. The DRS can prove to be superior to these as it also takes into account pre-operative insulin use and presence or absence of macro and micro vascular complications, in its criteria. Earlier the DRS has been used in patients undergoing Ileal Interposition couple with Sleeve gastrectomy (IISG) and Ileal Interposition coupled with Diverted Sleeve Gastrectomy (IIDSG). In this study we will specifically apply DRS in patients undergoing Mini Gastric Bypass surgery and evaluate the outcome of Type 2 Diabetes Mellitus at follow up.

AIMS AND OBJECTIVES

The primary aim of this study is to study the outcome of type 2 diabetes mellitus in patients undergoing mini gastric bypass using the Diabetes Remission Score Calculator.

REVIEW OF LITERATURE

According to the earliest reported literature, Henrikson V conducted a study in 1952 that showed that resection of small intestine resulted in weight loss in a 32 year old obese woman. The patient had a improved quality of life even though the weight loss was relatively less at 14 months.[22]

In 1963, Payne et al. performed jejunocolic shunts in 10 patients in which they bypassed distal jejunem, ileum and proximal colon with anastomosis of jejunum to transverse colon. The bypass was eventually reversed after a significant amount of weight loss had occurred. Significant weight loss occurred after the first surgery but many patients were seen to regain weight after the reversal. Along the abovementioned results, many patients experienced decreased absorption of potassium, calcium and vitamin B12.[23]

In 1969, Payne et al. conducted another study in 80 patients where they performed jejunoileal bypass instead of the previous jejunocolic bypass because of associated complications such as intractable diarrhea, electrolyte abnormalities etc. In the procedure they anastomosed proximal 14 inches of jejunem to distal 4 inches of ileum as a single stage procedure. This was associated with less complications as compared to the previous procedure and beneficial effects were noted in terms of permanent weight loss, diabetes, hypertension, edema, fertility and dyspnea.[24]

The first gastric bypass was performed by Mason et al. in 1967 in a series of 8 patients, where the proximal 20% of gastric fundus was anastomosed with jejunem 24 inches distal to the ligament of Treitz. The results showed significant weight loss in all the patients.[25]

A modified version of Mason's gastric bypass was performed by Alden et al in 1976 where he studied results in 100 patients. Similar weight loss was observed to jejuno-ileal bypass but the side effect profile was much better. Benefits to diabetic status of the patients was also noted.[26]

In 1977, Griffen et al. performed the Roux-en-Y gastrojejunostomy in which they divided the jejunem and distal limb was anastomosed with

the stomach in a retrocolic fashion and the proximal limb was anastomosed in an end to side fashion approx. 30cm distal to the gastro-jejunostomy. Similar weight loss profile was observed with less of long term sequalae.[27]

In 1979, Scopinaro et al. introduced biliopancreatic diversion in which they performed distal gastrectomy with closure of the duodenal stump. Transaction of the jejunem was done 20cm distal to the ligament of Treitz and distal part of the roux loop was used for gastrojejunostomy and the proximal jejunal loop was anastomosed to distal ileum in an end to side fashion. This showed significant weight loss in the range of 24 to 33 % at 6 and 12 months respectively.[28]

In 1993, Marceau et al. introduced a modification of Scopinaro's procedure by doing a parietal gastrectomy instead of a distal gastrectomy along the greater curvature thereby preserving the pylorus. The roux limb was anastomosed to the duodenum and the biliopancreatic limb was anastomosed the the ileum approx. 100cm proximal to the IC valve. This resulted in 10% weight loss of excess body weight and decreased side effects especially loose stools and flatulence.[29]

In a case series of 7 patients, Regan et al. (2003) performed a two stage laparoscopic Roux-en-Y gastric bypass. Average weight loss in the ranges of 33% of excess weight loss after the first procedure and 46% after the second procedure were noted.[30]

Ahmed et al. (1978) reported a case series of 24 patients in which they performed jejunoileal bypass and observed a fall in fasting blood sugar levels from 180+_47 preoperatively to 91+_17 post operative values.[31]

In a case series of 39 patients, Bourdages et al. (1994) performed vertical band gastroplasty and Roux-en-Y gastric bypass and reported a significant improvement of the diabetic status of seven out of nine patients suffering from type 2 diabetes mellitus. [32]

In 1995, in a case series of 62 patients, VBG, BPD & RYGB were performed by Murr et al. and it was observed that the diabetic medications in 62% of the patients showed significant reduction.[33]

In a case series of 330 patients, Pories et al (1995) performed gastric bypass and it was observed that 121 out of the 146 patients with type 2 diabetes mellitus showed normal levels of blood glucose, HbA1c and insulin levels post operatively.[34]

In 2003, Schauer et al. performed laparoscopic Roux-en-Y gastric bypass in 191 patients and evaluated them over a period of 5 years. It was observed that fasting blood sugar, HbA1c returned to normal levels in 83% of patients and were significantly improved in the remaining 17%. There was a significant reduction in insulin use, use of OHA's post operatively. It was also observed that patients with short duration of Type 2 DM and more weight loss after surgery were associated with greater remissions.[35]

In 2003 Sugermen et al. performed gastric bypass in 1025 patients, out of which 15% were suffering from T2DM and observed resolution of T2DM in 83% of patients at 1 year and 86% of patients at 5-7 years.[36]

In a review and meta analysis done by Henry Buchwald et al. (2009), they included 621 studies with 888 treatment arms and 135,246 patients out of which 103 treatment arms with 3188 patients reported on resolution of diabetes, that is, the resolution of the clinical and laboratory manifestations of type 2 diabetes. Nineteen studies with 43 treatment arms and 11,175 patients reported both weight loss and diabetes resolution separately for the 4070 diabetic patients in these studies. At baseline, the mean age was 40.2 years, body mass index was 47.9 kg/m2, 80% were female, and 10.5% had previous bariatric procedures. Meta-analysis of weight loss overall was 38.5 kg or 55.9% excess body weight loss. Overall, 78.1% of diabetic patients had complete resolution, and diabetes was improved or resolved in 86.6% of patients. Weight loss and diabetes resolution were greatest for patients undergoing biliopancreatic diversion/duodenal switch, followed by gastric bypass, and least for banding procedures. Insulin levels declined significantly postoperatively, as did hemoglobin A1c and fasting glucose values. Weight and diabetes parameters showed little difference at less than 2 years and at 2 years or more.[37]

In 2010, Hofso et al. conducted a 1 year controlled study in which they included morbidly obese patients and divided them into two groups, one of which underwent RYGB and the other group was treated with medical treatment and lifestyle modifications. It was observed that the mean 1-year weight loss in surgery group was 30% as compared to 8% in the medical group. T2DM remission was 70% in the surgery group as compared to 33% in the medical group.[38]

In 2011, Hayes et al. performed gastric bypass surgery in 130 morbidy obese diabetic patients with 1 year of follow up and observed that remission of diabetes occurred in 84% of the patients. The remaining 16% reported improvement in their diabetic status. They used 2 criterias for prediction of diabetes resolution namely pre operative HbA1c and diabetic status.[39]

In a study conducted by Augusto Tinoco et al. (2011), conducted in 30 patients, the aim of the study was to evaluate the short- and mid-term effects of laparoscopic sleeve gastrectomy (SG) with ileal interposition (II) in T2DM patients. The variables investigated were the feasibility of the procedure, remission/alleviation of the disease, morbidity, mortality, and weight loss. Patients were followed during a period of 6-18 months after surgery. Postoperatively, all patients experienced a significant weight loss: i.e., the mean body mass index (BMI) values prior to and following surgery were significantly different. Postoperative levels of glycosylated hemoglobin, fasting glucose, and fructosamine were significantly reduced from those detected prior to surgery. Remission of T2DM was observed in 80% of the patients over the follow-up period, and these subjects no longer required treatment with hypoglycemic drugs or diet. The remaining 20% of patients presented significant improvement in their condition but needed an oral hypoglycemic medication.[40]

In 2012, Heo et al. conducted a retrospective cohort study in two group of patients. One group of 261 patients underwent bariatric surgery and the other group of 224 patients was treated with medical therapy and lifestyle modification. Remission of diabetes was seen in 57% of patients in surgery group as compared to 10% in the medical group.[41]

In a study conducted by Dixon et al. in 2013, 103 patients who underwent bariatric surgery were studied and followed up for 1 year. They used two variables to derive a risk calculator: BMI & duration of diabetes. The cut off points for BMI was >27 and that of duration of diabetes was <7 years and patients were classified on basis of presence of factors as 0,1 or 2. It was observed that remission of diabetes occurred in 62% of patients having 2 factors, 26% of patients having 1 factor and 13% of patients having 0 factors.[42]

Marco Milone et al. (2013) conducted a study in 53 diabetic patients who underwent sleeve gastrectomy and mini gastric bypass. A total of 15 subjects underwent SG (48.4%), and 16 underwent MGB (51.6%). It was observed that remission of diabetes was higher in MGB group as compared to those who underwent sleeve gastrectomy.[43]

In a study conducted by Wei-Jei Lee et al. (2013), they evaluated 63 patients and identified 4 factors that predicted the success of T2DM remission after bariatric surgery in this cohort: body mass index, C-peptide level, T2DM duration, and patient age. They concluded that a total of 48 T2DM remissions occurred among the 63 patients.[44]

In a study conducted by Sayeed Ikramuddin et al. (2013), 120 patients were taken and given medical therapy, out of these 120 patients, 60 were randomly assigned to undergo roux-en-y gastric bypass. After 12 months, 28 in the gastric bypass group and 11 in the medically managed group, achieved the primary end points. The surgically managed patients required 3.0 fewer medications and lost 26.1% vs 7.9% of their initial body weigh compared with the lifestyle-medical management group, thus concluding that in mild to moderately obese patients with type 2 diabetes, adding gastric bypass surgery to lifestyle and medical management was associated with a greater likelihood of achieving the composite goal.[45]

Surendra Ugale et al. (2014) conducted a retrospective study in 75 patients out of which 46 underwent Ileal Interposition coupled with sleeve gastrectomy (IISG) and 29 patients underwent Ileal Interposition coupled with Diverted Sleeve Gastrectomy (IIDSG). The primary outcome was to measure remission of T2DM (HbA1c <6.5% and not requiring

hypoglycemic drugs). Seven preoperative clinical variables were identified (age, duration of diabetes, BMI, presence of micro and macro vascular complications, preoperative use of insulin and C-peptide levels) and Diabetes Remission Score (DRS) was calculated. The DRS (7-14) was compared between the patients with and without remission in both the surgery groups. It was observed that DRS was significantly lower in patients with remission than without remission (9.7 ± 0.8 versus 12.0 ± 0.5, $p < 0.0001$). Preoperative DRS can be a useful tool to select the type of surgical procedure and to predict the postoperative diabetes remission.[21]

Christopher d still et al. (2014), conducted a study in 690 patients in 2013 using the DiaRem score calculator to predict the remission of type 2 DM after RYGB and found that 63% achieved partial / complete remission.[46]

In a study conducted by Philip R. Schauer et al. (2014), outcomes were assessed 3 years after the randomization of 150 obese patients with uncontrolled type 2 diabetes to receive either intensive medical therapy alone or intensive medical therapy plus Roux-en-Y gastric bypass or sleeve gastrectomy. Among obese patients with uncontrolled type 2 diabetes, 3 years of intensive medical therapy plus bariatric surgery resulted in glycemic control in significantly more patients than did medical therapy alone.[47]

In a study conducted by Geltrude Mingrone et al. (2015), 60 patients were randomly assigned to receive either medical or surgical treatment. Out of those, 20 received medical treatment & 40 underwent bariatric surgery. Out of those 53 patients completed 5 years follow up and it was found that 19 of the 38 surgically treated patients maintained diabetes remission at 5 years compared with none out of the 15 medically treated patients.[48]

In a study conducted by Wei-Jei Lee et al. (2015), a total of 157 patients with T2 DM (82 women and 75 men) with morbid obesity (mean body mass index 39.0 +- 7.4 kg/m2) who underwent Laparoscopic Sleeve Gastrectomy from 2006 to 2013 were selected for the present study and the remission of type 2 DM was evaluated using the ABCD score. The ABCD score is composed of the patient’s age, body mass index, C-

peptide level, and duration of T2 DM (yr). At 12 months after surgery, 85 of the patients had complete follow-up data. The weight loss was 26.5% and the mean HbA1c decreased from 8.1% to 6.1%. A significant number of patients had improvement in their glycemic control, including 45 (52.9%) patients who had complete remission (HbA1c o6.0%), another 18 (21.2%) who had partial remission (HbA1c o6.5%), and 9 (10.6%) who improved (HbA1c o7%). Patients who had T2 DM remission after surgery had a higher ABCD score than those who did not. Patients with a higher ABCD score were also at a higher rate of success in T2 DM remission.[49]

In a study conducted by M Musella et al. (2016), 206 patients were evaluated at 1 year follow up having T2DM out of which 96 underwent mini gastric bypass and 110 patients underwent sleeve gastrectomy. After 1 year of follow up 82 out of 96 patients (85.4%) who underwent mini gastric bypass and 67 out of 110 patients (60.9%) who underwent sleeve gastrectomy were in remission. They concluded that mini gastric bypass was better at controlling T2DM than sleeve gastrectomy.[50]

In a study conducted by Ali Aminian et al. (2017), they studied a total of 659 patients with T2DM who underwent RYGB and sleeve gastrectomy. Four independent predictors of long-term remission including preoperative duration of T2DM, preoperative number of diabetes medications, insulin use, and glycemic control (HbA1C < 7%) were used to develop the Individualized Metabolic Surgery (IMS) score and concluded that diabetes remission (HbA1C <6.5% off medications) was observed in 49% after RYGB and 28% after SG.[51]

In a study conducted by Nicola Scopinaro et al. (2017), A cohort of 135 consecutive T2DM patients with a wide range of body mass index (BMI) at more than 5 years following biliopancreatic diversion (BPD) was considered. It was concluded that BMI and insulin therapy at the time of surgery are associated with the probability of T2DM long lasting remission and could be used as solid predictors before surgery.[52]

In a study conducted by Jung-Chien Chen et al. (2018), A total of 310 T2D patients who underwent gastric bypass and sleeve gastrectomy at an academic center in Taiwan and had a minimum 5-year follow-up

(2004–2012) were examined for the predictive power of complete remission using the IMS and the ABCD scoring systems. At the 5-year follow-up, weight loss was 27.5%, with mean body mass index decreasing from 37.8 to 27.9 kg/m2, mean glycated hemoglobin decreased from 8.6% to 6.1%, and prolonged remission of T2D achieved in 224 (72.3%) T2D patients. Remission rates were higher in patients who underwent gastric bypass than in those who underwent sleeve gastrectomy (73.6% versus 66.1%; P ¼ .04), regardless of T2D severity, and were 96%, 68%, and 16% in patients with IMS mild, moderate, and severe scores, respectively. Although both scores predicted the success of surgery, the ABCD was better in patients with IMS moderate scores, thus concluding that Metabolic surgery is an option for T2D patients with obesity and that the ABCD score may be better at predicting T2D remission after metabolic surgery compared with the IMS score.[53]

Digvijay Singh Sohal et al. (2020) conducted a study in 60 patients undergoing bariatric surgery and followed up at 3 and 6 months. They used the ABCD score to predict the remission of diabetes after bariatric surgery. At 6 months, the mean % Estimated weight loss was 62.74. Significant improvements were noted in FBS (193.05 to 107.97), in HbA1C (8.22 to 6.17), dose of OHAs (1.97 to none), and insulin (32.86 to 5.66). Patients who attained remission were younger, with shorter duration of diabetes and higher C-peptide levels. The preoperative BMI or the % EWL were not predictive of diabetes remission. Higher ABCD scores were significantly associated with higher rates of diabetes remission.[54]

MATERIALS AND METHODS

Information will be collected via predesigned proforma, complete clinical examination will be done and patients undergoing mini gastric bypass will be analysed in this time bound study. (Extending from January 2020 to June 2021). Patients unwilling for treatment or whose reports are not available will be excluded.

SOURCE OF DATA

Data shall be collected from all patients undergoing mini gastric bypass surgery, who are admitted during the given time period will be taken for study considering the inclusion and exclusion criteria.

METHOD OF COLLECTION OF DATA

Information will be collected through predesigned pretested proforma for each patient. All patients will be interviewed as per the proforma and a complete clinical examination will be done.

Sample size - Time bound study.

Inclusion criteria-

- Patients of type 2 DM having BMI>35 kg/m2 undergoing Mini Gastric Bypass

-Patient or Guardian of the patient giving informed consent for enrolment in the study

Exclusion criteria-

- Patients suffering from diabetes mellitus type 1
- Patients suffering from any malignancy.
- Patients suffering from Schizophrenia.
- Any previous h/o bariatric surgery
- Patients not motivated enough, unwilling for treatment or whose reports are not available.

Period of follow-up: 180 days

Duration of the Study: 1st January 2020 to 30th June 2021 (Including 6 months followup)

Method of collection of data:

Pre operatively all patients underwent the following:

Anthropometric measurements:

- Height
- Weight
- BMI – calculated as ratio of weight in kg to height in meter squared

Laboratory investigations:

- FBS (mg/dL):
- HbA1c (%):
- C-Peptide (ng/ml):

Pre anaesthetic checkup:

A complete and detailed pre anaesthetic check was done by the anaesthesia team one day prior to surgery. Detailed history and physical examination was done. Routine investigations like complete blood count, renal and liver function tests, coagulation profile, ECG's, 2D echo, random blood sugar were done prior to surgery. Appropriate consults were taken by cardiology, respiratory and endocrinology teams wherever needed.

Pre-medication:

All the patients were kept fasting for at least 6-8 hours pre operatively. The following medications were given one night prior to surgery:

Tab Alprazolam 0.25mg at night and on morning of surgery at 6 am to all patients

Tab Ranitidine 150mg at night before surgery and on morning of surgery orally with one sip of water.

Operative technique:

The surgeon stands on the patient's right side, and the assistant surgeon stands on the patient's left side. The patient is placed on the operating table in a supine position, which is inclined to a maximum reverse Trendelenburg position and with the left side maximum up. This requires secure patient immobilization onto the table. The surgeon should slowly test this position prior to draping the patient, to confirm security of positioning and stability of the vital signs. Carbon dioxide pneumo-peritoneum is created. The intra-abdominal pressure is maintained at 14–17 mm Hg. The "Classic Rutledge Technique" includes: Five ports

placed in a “diamond-shaped” pattern in the upper abdomen. First, a 12 mm camera port in the midline approximately two handbreadths below the xiphi-sternum (ignoring the location of umbilicus). Second, a 12 mm port in between the right midclavicular and anterior axillary line, 2–3 fingerbreadths below the right costal margin. Third, a 12 mm midline port (the surgeon's left hand working port) 2–3 finger breadths below the xiphi-sternum. Fourth, a 12 mm port in left midclavicular line two to three finger breadths below the patient's left costal margin as the surgeon's right-hand working port. Fifth, a 5 mm assistant port in the left anterior axillary line, 2–3 finger breadths below the left costal margin. A 30° angle telescope is used routinely to provide better visualization of the gastro-esophageal junction. The restriction of MGB comes from rapid gastric emptying into the jejunum. The surgical procedure is akin to the Collis Gastroplasty. The MGB pouch should be no more obstructive than the esophagus itself. Thus, the Gastric tube should as be wide as the esophagus and not tight or obstructive as in a sleeve, and similarly the gastro-jejunostomy should be large and non-obstructive. A long gastric tube is created with the use of an Endo-stapler approximately 1.5cm to the left of lesser curvature from the angle of His to the antrum. An antecolic loop gastroenterostomy is created approximately 200cm distal to the Ligament of Treitz using Endo-stapler and closed with continuous sutures. A hemovac drain is placed in the lesser sac.

PICTURE 1: PORT SITES

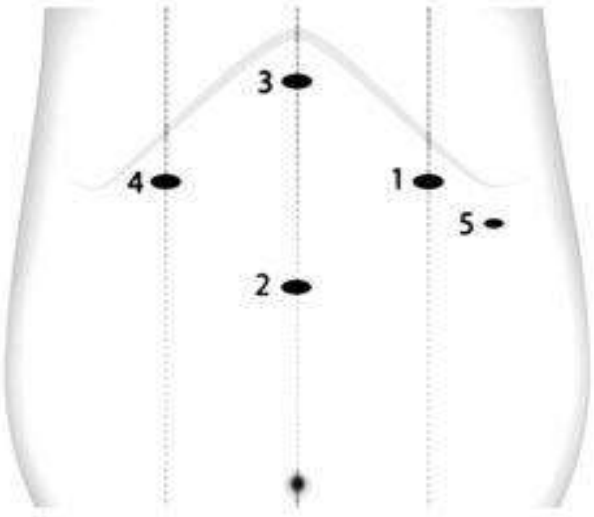

Fig. 1. Port sites.

PICTURE 2: FIRST FIRING OF STAPLER

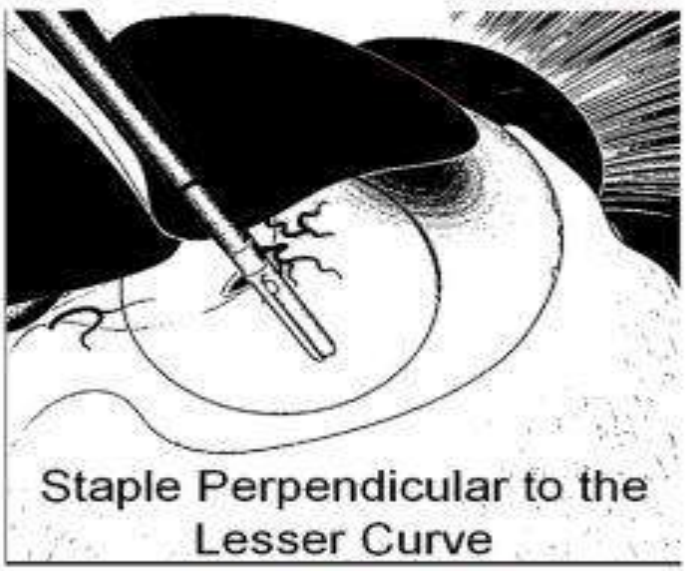

Fig. 2. First firing of staple.

PICTURE 3: MGB GASTRIC POUCH

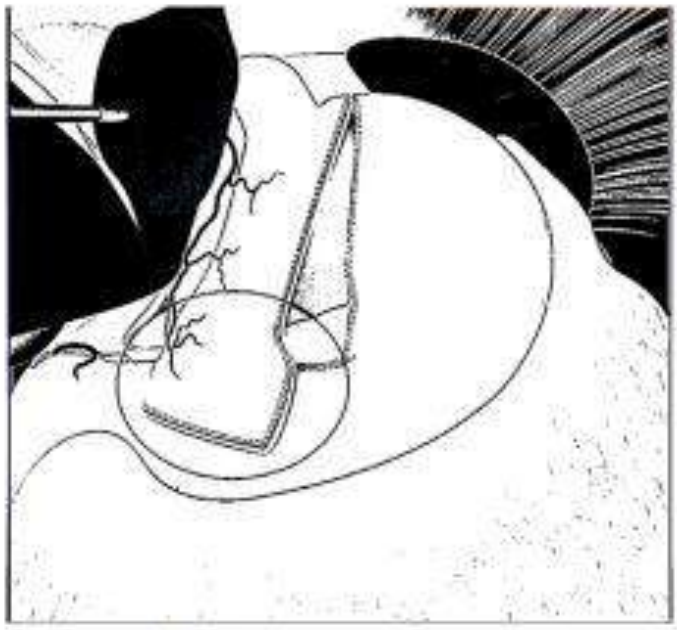

Fig. 3. MGB Gastric Pouch, what's important !.

PICTURE 4: STAPLED ANASTOMOSIS

Fig. 4. Stapled anastomosis.

TABLE 2: DIABETIC REMISSION SCORE (DRS)

Parameter	Score	
	1	2
• Age (yrs)	30-60	<30 or >60
• Body mass index (kg/m^2)	>= 27	<27
• Duration of type 2 DM (yrs)	<10	>10
• Microvascular complications	no	Yes
• Macrovascular complications	no	yes
• Preoperative insulin use	no	yes
• C – peptide levels (ng/ml)	>0.5	<0.5

Follow up:

Patients were followed up at 1, 3 and 6 months post operatively and the following parameters were recorded – weight, FBS, HbA1c, C-peptide levels, dose of insulin and no. of OHA's needed. Complete remission of diabetes is defined as HbA1c of <6% without the use of insulin or OHA's and partial remission is defined as HbA1c <6.5%. The remission rate

was studied with respect to pre operative Diabetic Remission Score (DRS) of the patient.

Statistical analysis:

Data will be described in terms of range; mean ±standard deviation (± SD), frequencies (number of cases) and relative frequencies (percentages) as appropriate. All statistical calculations will be done using SPSS (Statistical Package for the Social Science) SPSS 21 version statistical program for Microsoft Windows.

RESULTS AND OBSERVATIONS

Present study was conducted in department of surgery DMCH Ludhiana, over a period of 1.5 years. 24 diabetic obese patients underwent mini gastric bypass and were followed up for period of 6 months. Results of the present study are presented below:

TABLE 3: AGE DISTRIBUTION OF THE PATIENTS

Age	No. of cases	Percentage
< 40	10	41.7%
41-50	5	20.8%
51-60	7	29.2%
> 60	2	8.3%

Maximum patients who underwent surgery were <40 (41.7%) years of age, followed by patients in 50-60(29.2%) years, 41-50 years (20.8%) and least patients were present in age group >60years (8.3%) years

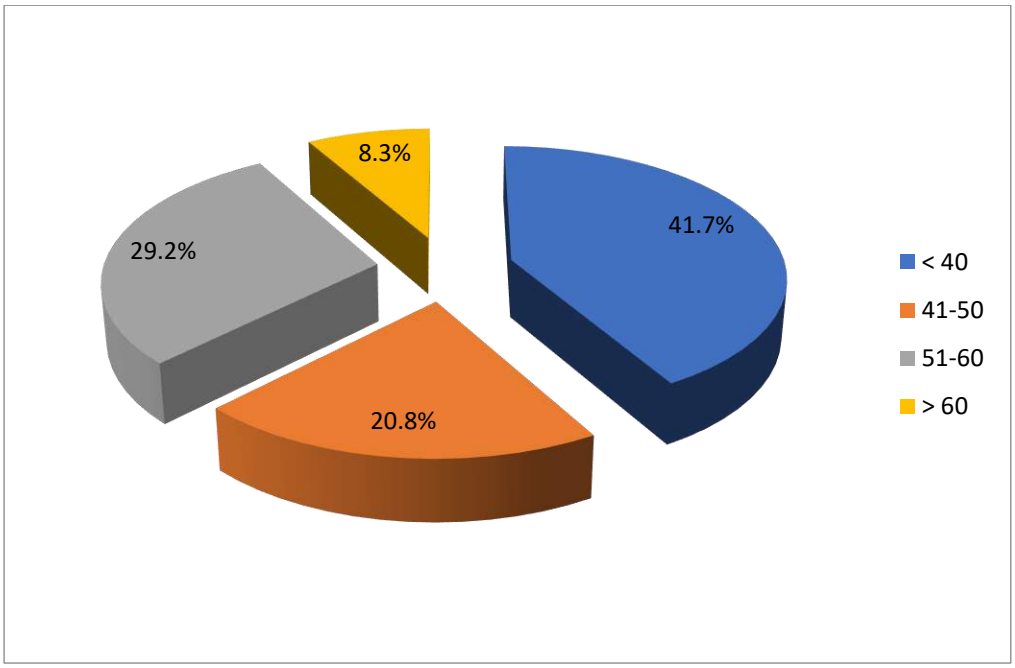

FIGURE 1: AGE DISTRIBUTION OF THE PATIENTS

TABLE 4: SEX DISTRIBUTION IN PATIENTS

Sex	No. of cases	Percentage
F	13	54.2%
M	11	45.8%
Total	24	100.0%

There was slight predilection in number of females in the study. 54.2% patients were females while 45.8% patients were males.

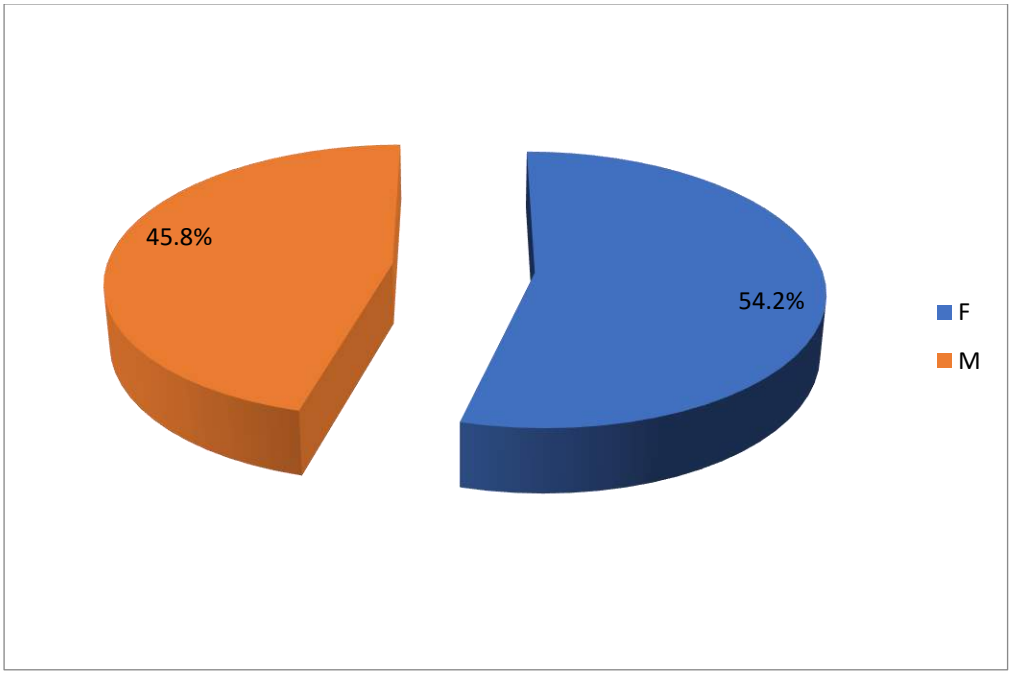

FIGURE 2: SEX DISTRIBUTION IN PATIENTS

TABLE 5: DISTRIBUTION OF PATIENTS ACCORDING TO COMORBIDITY

Co - morbidities	No. of cases	Percentage
HTN	6	25.0%
HTN, CAD	1	4.2%
HTN, OSA	2	8.3%

Maximum patients in present study had Hypertension (HTN) alone (25%) followed by HTN with Obstructive sleep apnea (OSA) (8.3%) and HTN with CAD (4.2%)

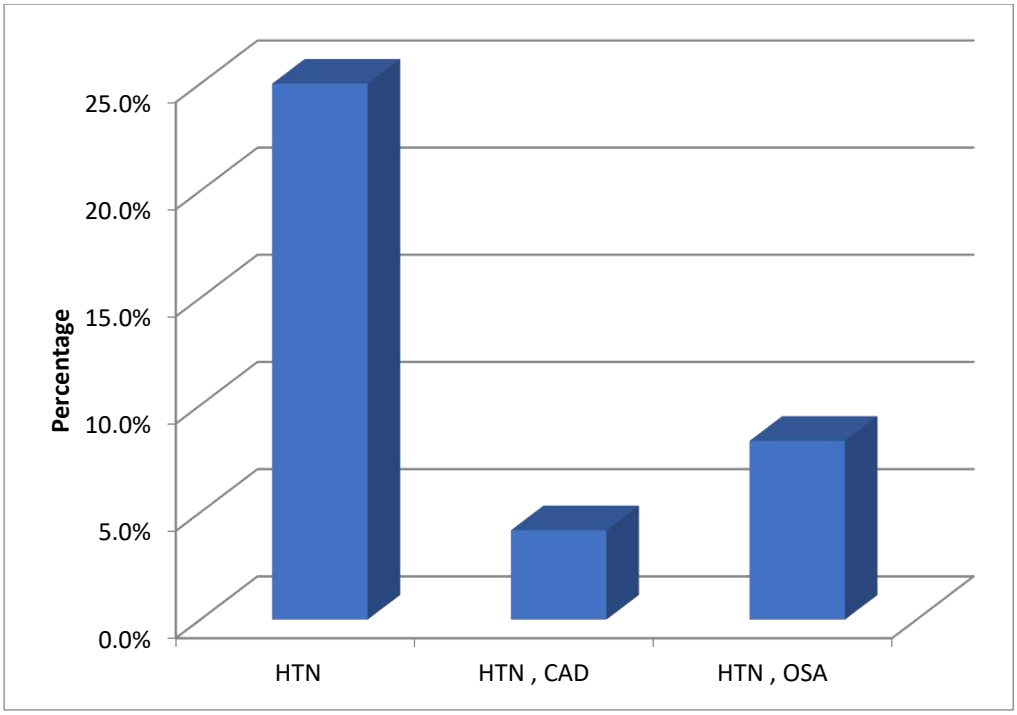

FIGURE 3: DISTRIBUTION OF PATIENTS ACCORDING TO COMORBIDITY

TABLE 6: DISTRIBUTION OF PATIENTS ACCORDING TO OPTIMAL ORAL HYPOGLYCAEMIC AGENTS INTAKE PREOPERATIVELY

OHA (PREOP)	No. of cases	Percentage
-	7	29.2%
1	7	29.2%
2	5	20.8%
3	1	4.2%
4	3	12.5%
5	1	4.2%
Total	24	100.0%

7(29.2%) patients were not on OHA, while 7(29.2%) patients were taking 1 OHA. 5 patients (20.8%) were on 2 OHA's followed by 1 (4.2%) patients who was on 3 OHA's. 3 (12.5%) patients were taking 4 and 1 (4.2%) patient was taking 5 OHA's.

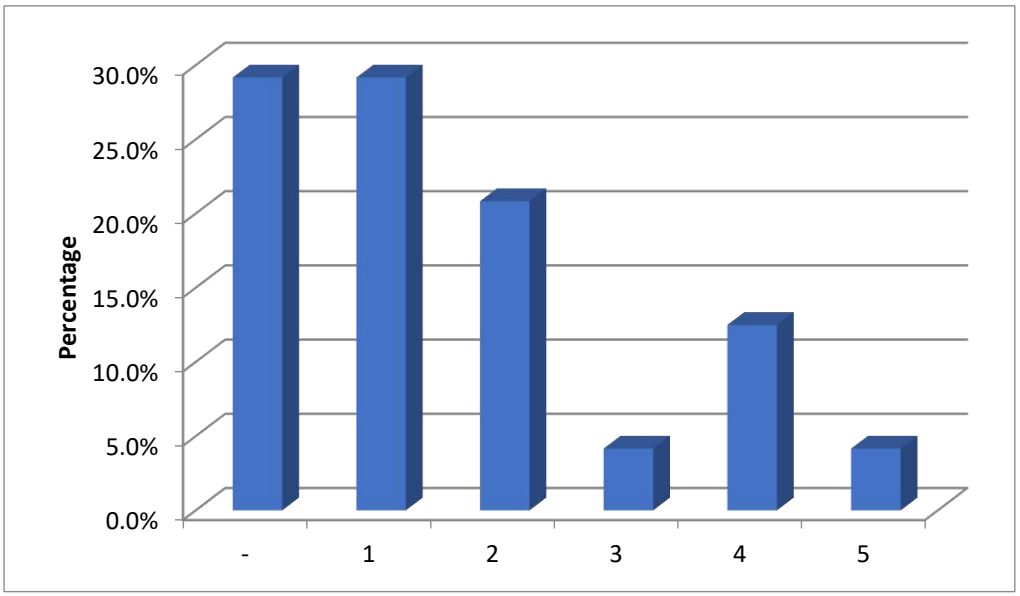

FIGURE 4: DISTRIBUTION OF PATIENTS ACCORDING TO OPTIMAL ORAL HYPOGLYCAEMIC AGENTS INTAKE

TABLE 7: DISTRIBUTION OF PATIENTS ACCORDING TO MICROVASCULAR COMPLICATIONS

Presence of micro-vascular complications	No. of cases	Percentage
NO	13	54.2%
YES	11	45.8%
Total	24	100.0%

45.8% patients in the study showed the presence of microvascular complications

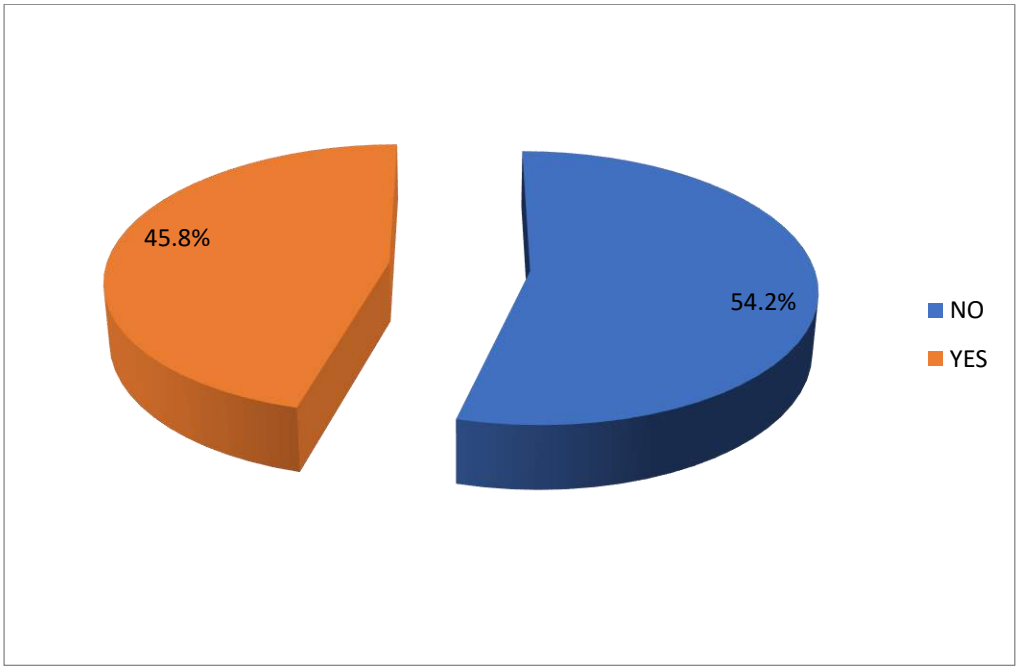

FIGURE 5: DISTRIBUTION OF PATIENTS ACCORDING TO MICROVASCULAR COMPLICATIONS

TABLE 8: PRE OPERATIVE INSULIN USE

Pre operative insulin use (total units)	No. of cases	Percentage
-	15	62.5%
12	1	4.2%
18	1	4.2%
26	1	4.2%
28	1	4.2%
30	2	8.3%
42	2	8.3%
46	1	4.2%
Total	24	100.0%

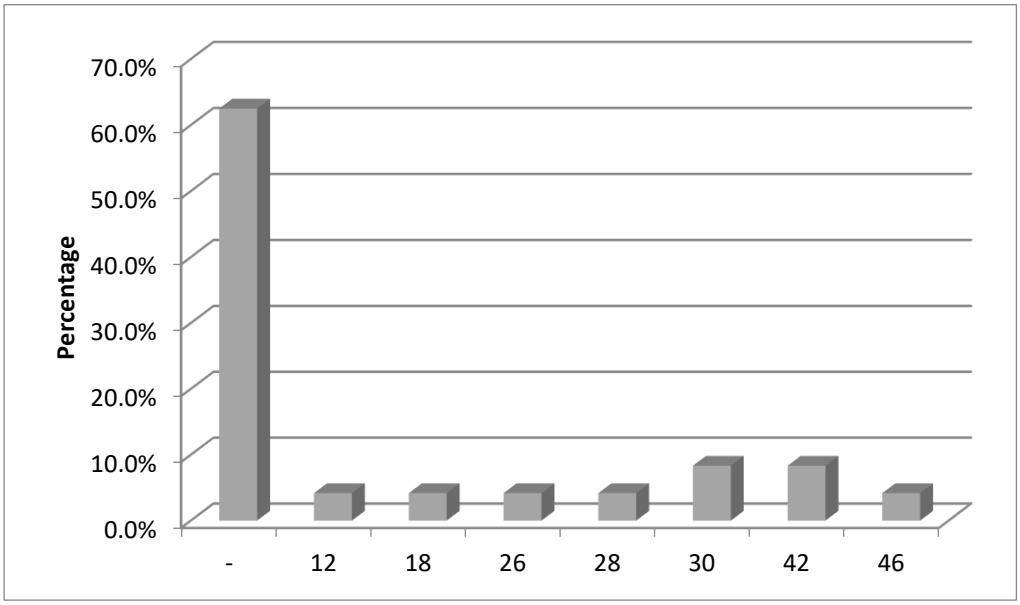

FIGURE 6: PRE OPERATIVE INSULIN USE

TABLE 9: DISTRIBUTION OF PATIENTS ACCORDING TO CLINICAL MACROVASCULAR COMPLICATIONS

Presence of clinical macrovascular complications	No. of cases	Percentage
NO	16	66.7%
YES	8	33.3%
Total	24	100.0%

33.33 % patients in the study showed the presence of clinical macrovascular complications

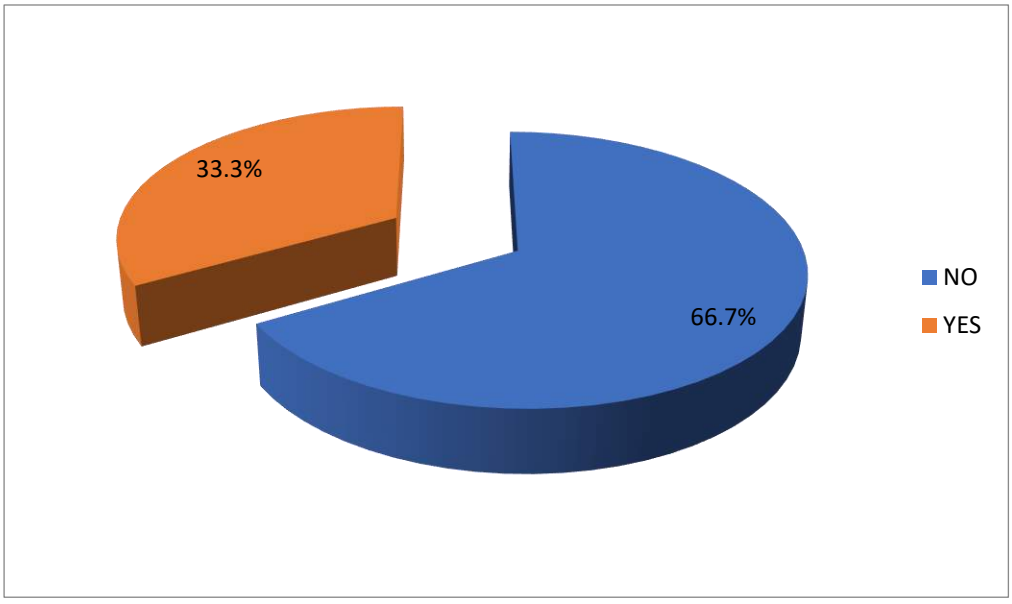

FIGURE 7: DISTRIBUTION OF PATIENTS ACCORDING TO CLINICAL MACROVASCULAR COMPLICATIONS

TABLE 10: VARIOUS BASELINE CHARACTERISTICS PREOPERATIVELY

	N	Minimum	Maximum	Mean	SD
Age	24	36.00	74.00	46.33	9.49
Duration of type 2 diabetes mellitus	24	0.50	26.00	7.07	6.82
Pre operative insulin use (total units)	9	12.00	46.00	30.44	11.35
Height (m)	24	1.38	1.90	1.62	0.12
C-Peptide (ng/ml)	24	1.10	11.00	5.29	2.90
Diabetes Remission Score	24	7.00	12.00	8.58	1.53

Above table shows baseline characteristic of various variables assessed in the study population

TABLE 11: DISTRIBUTION OF PATIENTS ACCORDING TO OPTIMAL ORAL HYPOGLYCAEMIC AGENTS INTAKE AT 1 MONTH

OHA's dose_At 1 month	No. of cases	Percentage
-	14	58.3%
1	2	8.3%
2	5	20.8%
4	3	12.5%
Total	24	100.0%

14 (58.3%) patients were not on OHA, while 2 (8.3%) patients were taking 1 OHA. 5 patients (20.8%) were on 2 OHA's followed by 3 (12.5%) patients who were on 4 OHA.

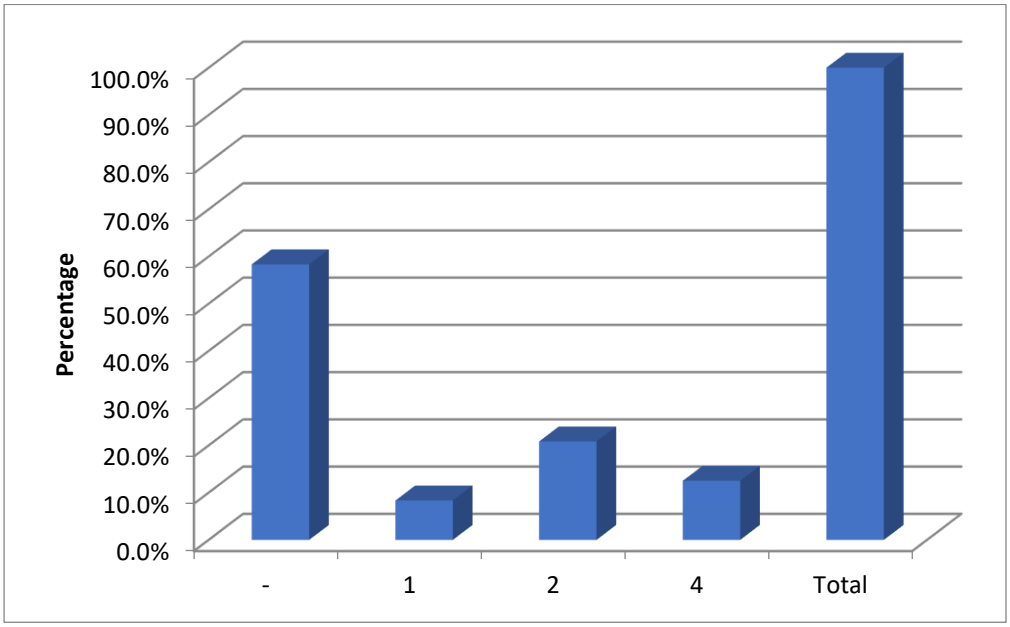

FIGURE 8: DISTRIBUTION OF PATIENTS ACCORDING TO OPTIMAL ORAL HYPOGLYCEMIC AGENTS INTAKE AT 1 MONTH

TABLE 12: DISTRIBUTION OF PATIENTS ACCORDING TO OPTIMAL ORAL HYPOGLYCAEMIC AGENTS INTAKE AT 3 MONTHS

OHA's dose_At 3 months	No. of cases	Percentage
-	18	75.0%
1	1	4.2%
2	2	8.3%
3	3	12.5%
Total	24	100.0%

18 (75%) patients were not on OHA's, while 1 (4.2%) patient was taking 1 OHA. 2 patients (8.3%) were on 2 OHA's followed by 3 (12.5%) patients who were on 3 OHA's.

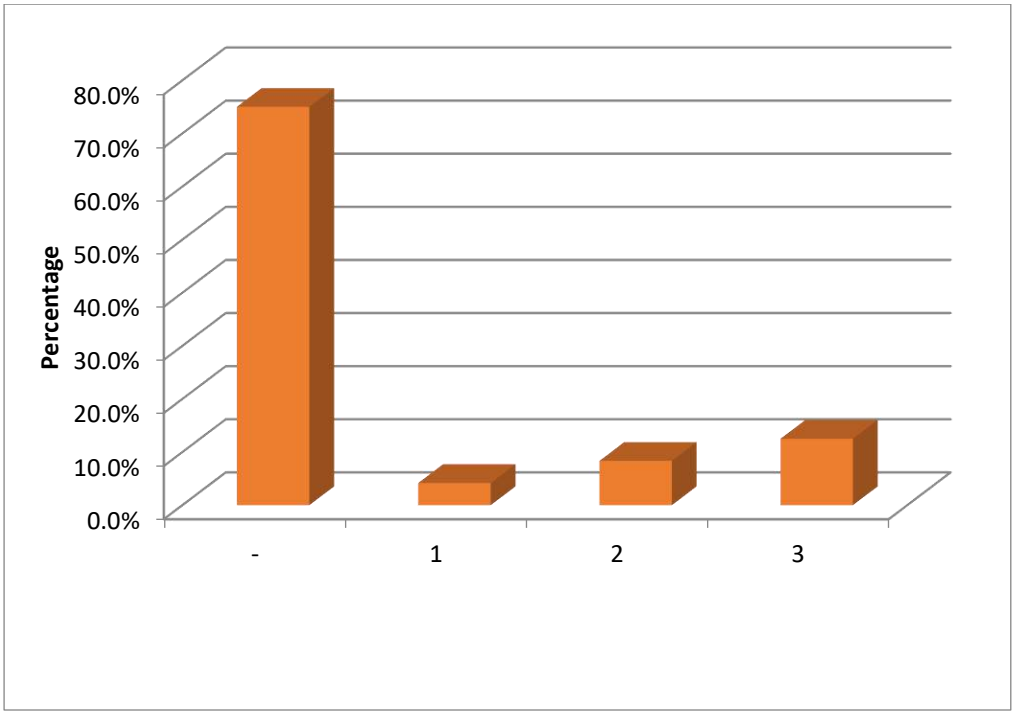

FIGURE 9: DISTRIBUTION OF PATIENTS ACCORDING TO OPTIMAL ORAL HYPOGLYCEMIC AGENTS INTAKE AT 3 MONTHS

TABLE 13: DISTRIBUTION OF PATIENTS ACCORDING TO OPTIMAL ORAL HYPOGLYCEMIC AGENTS INTAKE AT 6 MONTHS

OHA's dose At 6 months	No. of cases	Percentage
-	19	79.2%
1	1	4.2%
2	2	8.3%
3	2	8.3%
Total	24	100.0%

19 (79.2%) patients were not on any OHA's, while 1 (4.2%) patient was taking 1 OHA. 2 patients (8.3%) were on 2 OHA's followed by 2 (8.3%) patients who were on 3 OHA's.

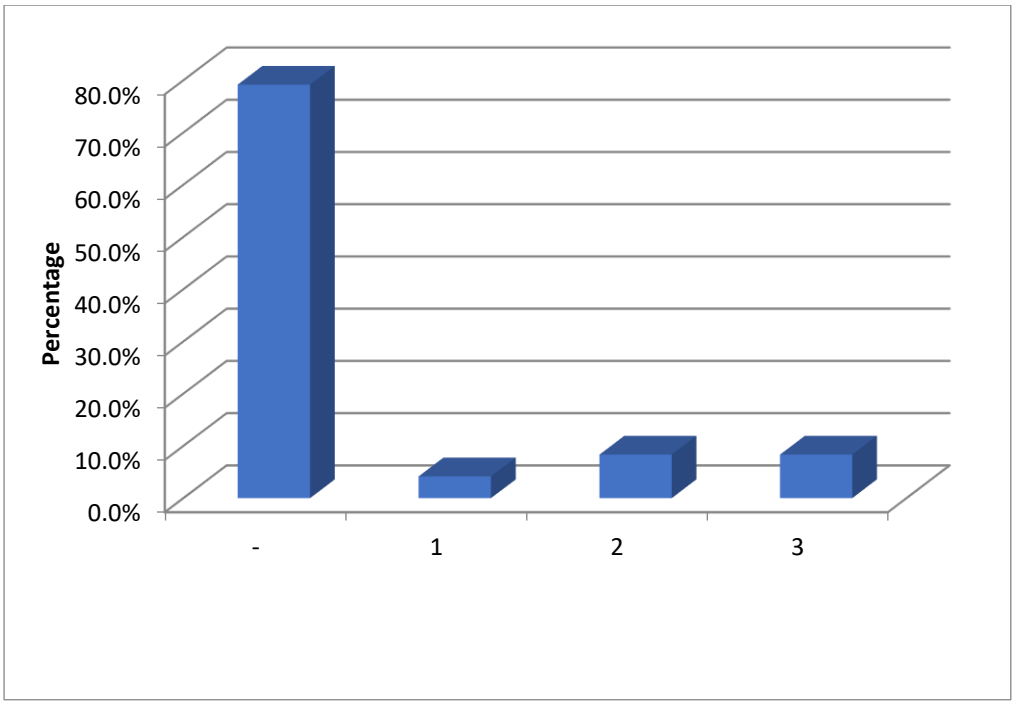

FIGURE 10: DISTRIBUTION OF PATIENTS ACCORDING TO OPTIMAL ORAL HYPOGLYCEMIC AGENTS INTAKE AT 6 MONTHS

TABLE 14: DISTRIBUTION OF PATIENTS ACCORDING TO INSULIN USAGE AT DIFFERENT TIME INTERVALS

Pre operative insulin use (total units)	No	15	62.50%
	Yes	9	37.50%
Insulin dose_At 1 month	No	16	66.70%
	Yes	8	33.30%
Insulin dose_At 3 months	No	17	70.80%
	Yes	7	29.20%
Insulin dose_At 6 months	No	18	75%
	Yes	6	25%

It was observed that preoperatively 9 (37.50%) patients were on insulin while at 1st month 7(33.30%) were on insulin. At the end of 3rd month 29.20% patients were on insulin while at the end of 6 months 25% were on insulin.

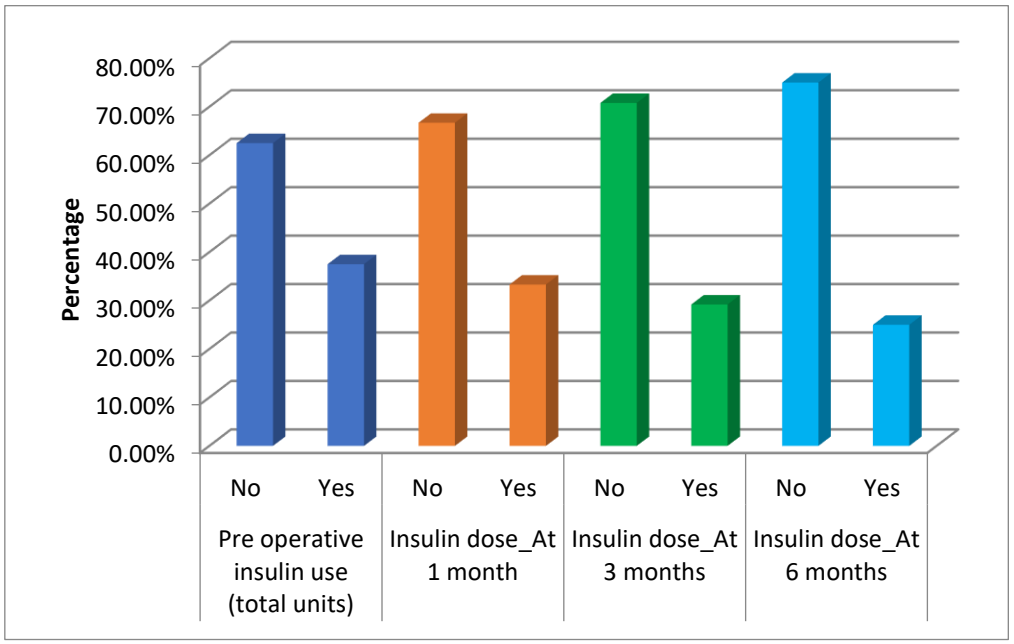

FIGURE 11: DISTRIBUTION OF PATIENTS ACCORDING TO INSULIN USAGE AT DIFFERENT TIME INTERVALS

TABLE 15: DRS GROUPS ACCORDING TO SCORE

	N	Minimum	Maximum	Mean	SD
Diabetes Remission Score	24	7.00	12.00	8.58	1.53
Diabetes Remission Score group	24	1.00	2.00	1.42	0.50

TABLE 16: COMPARISON OF WEIGHT AT DIFFERENT TIME INTERVALS

	Mean	SD	t	p-value	Mean difference	SD difference
Weight (kg)	114.70	17.35				
Weight (kg)_At 1 month	108.33	16.28	12.233	<0.001	6.37	2.55
Weight (kg)_At 3 months	96.17	16.13	11.528	<0.001	18.54	7.88
Weight (kg)_At 6 months	87.54	15.39	12.532	<0.001	27.16	10.62

On comparing weight of the patients preoperatively (114.70±17.35) and at 1 month, 3 month and 6 month it was observed that the weight of the person was significantly less at 1 month (108.33±16.28), 3 month (96.17±16.13) and 6 month (87.54±15.39).

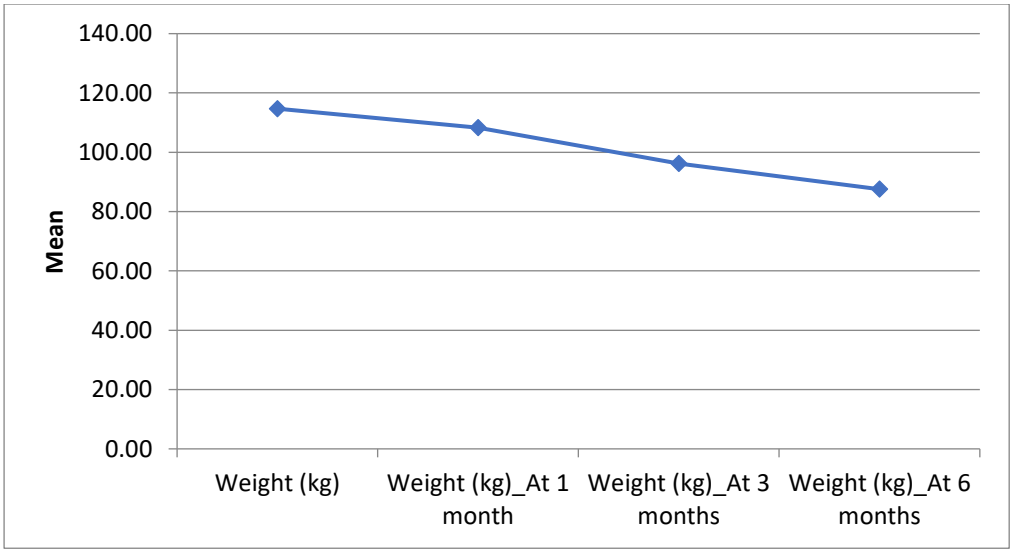

FIGURE 12: COMPARISON OF WEIGHT AT DIFFERENT TIME INTERVALS

TABLE 17: COMPARISON OF BMI AT DIFFERENT TIME INTERVALS

	Mean	SD	t	p-value	Mean difference	SD difference
BMI (kg/m2)	43.88	6.56				
BMI (kg/m2)_At 1 month	41.15	5.92	11.739	<0.001	2.73	1.14
BMI (kg/m2)_At 3 months	35.74	4.79	10.640	<0.001	8.14	3.75
BMI (kg/m2)_At 6 months	32.05	4.05	11.576	<0.001	11.82	5.00

On comparing BMI of the patients preoperatively (43.88±6.56) and at 1 month, 3 month and 6 month it was observed that the BMI of the person was significantly less at 1 month (41.15±5.92), 3 month (35.74±4.79) and 6 month (32.05±4.05).

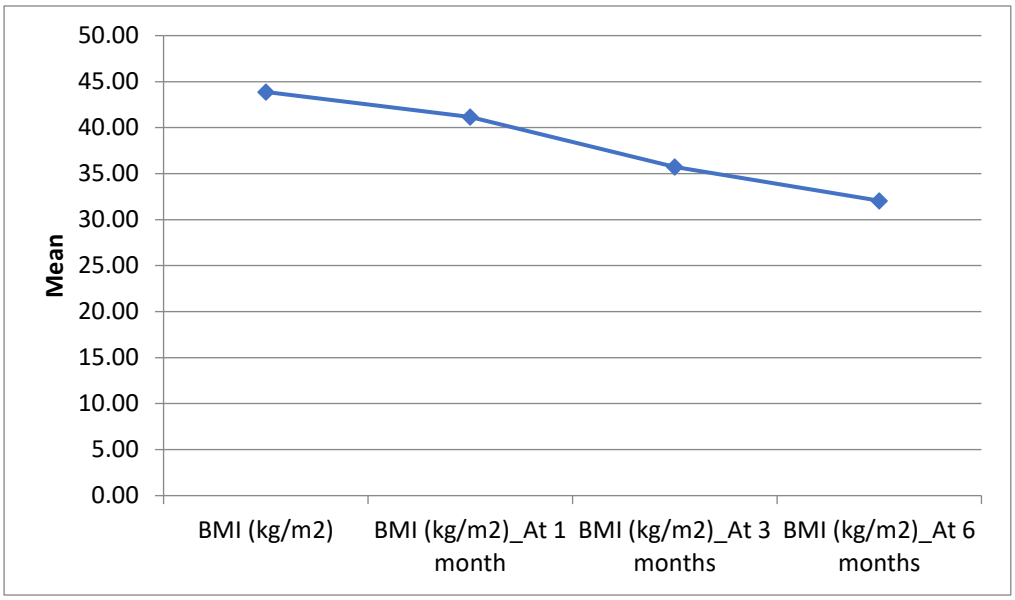

FIGURE 13: COMPARISON OF BMI AT DIFFERENT TIME INTERVALS

TABLE 18: COMPARISON OF FBS AT DIFFERENT TIME INTERVALS

	Mean	SD	t	p-value	Mean difference	SD difference
FBS (mg/dL)	190.33	48.56				
FBS (mg/dL)_At 1 month	167.58	44.54	8.625	<0.001	22.75	12.92
FBS (mg/dL)_At 3 months	144.75	44.33	9.524	<0.001	45.58	23.45
FBS (mg/dL)_At 6 months	123.42	36.70	8.732	<0.001	66.92	37.54

On comparing FBS of the patients preoperatively (190.33±48.56) and at 1 month, 3 month and 6 month it was observed that the FBS of the person was significantly less at 1 month (167.58±44.54), 3 months (144.75±44.33) and 6 months (123.42±36.70).

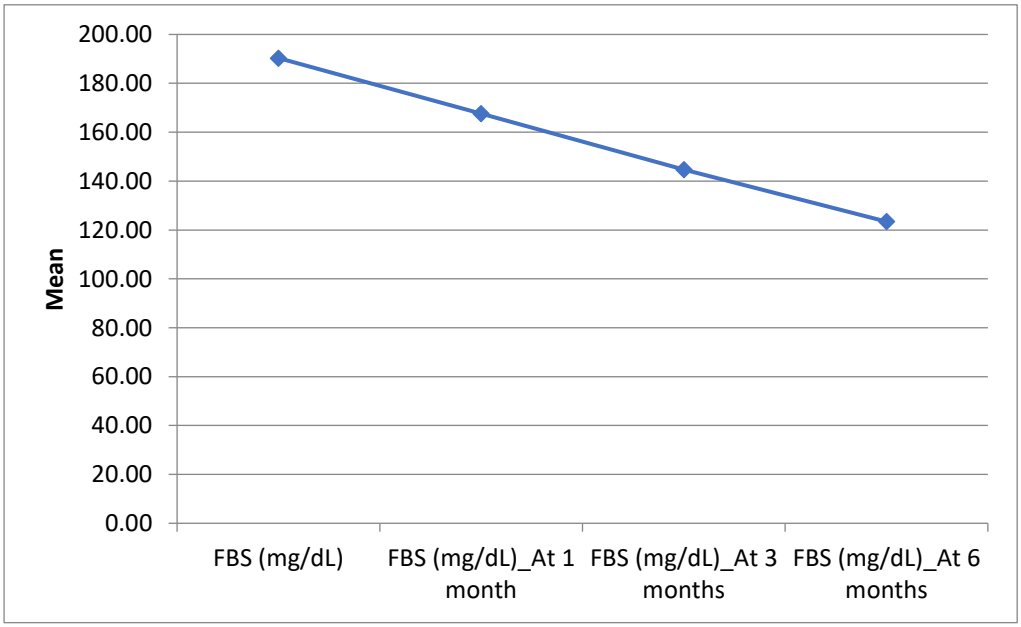

FIGURE 14: COMPARISON OF FBS AT DIFFERENT TIME INTERVALS

TABLE 19: COMPARISON OF HbA1c (%) AT DIFFERENT TIME INTERVALS

	Mean	SD	t	p-value	Mean difference	SD difference
HbA1c (%)	8.09	1.41				
HbA1c (%)_At 1 month	7.73	1.38	11.796	<0.001	0.37	0.15
HbA1c (%)_At 3 months	7.12	1.27	10.745	<0.001	0.98	0.44
HbA1c (%)_At 6 months	6.44	1.11	11.941	<0.001	1.65	0.68

On comparing HbA1c(%) of the patients preoperatively (8.09±1.41) and at 1 month, 3 month and 6 month it was observed that the HbA1c (%) of the person was significantly less at 1 month (7.73±1.38) , 3 months (7.12±1.27) and 6 months (6.44±1.11).

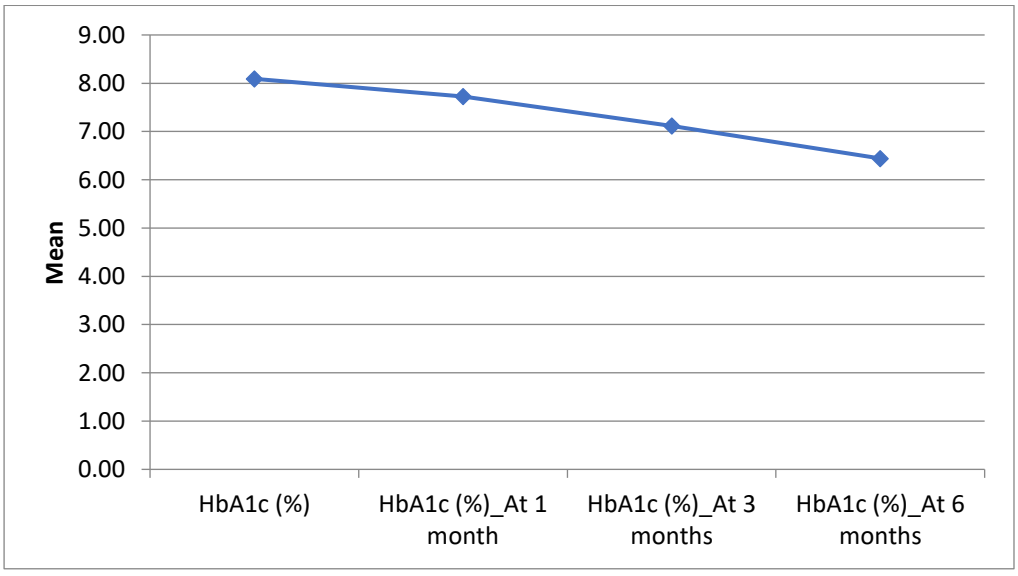

FIGURE 15: COMPARISON OF HbA1c (%) AT DIFFERENT TIME INTERVAL

TABLE 20: COMPARISON OF MEAN WEIGHT ACCORDING TO DIABETES REMISSION SCORE(DRS)

Diabetes Remission Score(DRS)	< 8		> 8		t	p-value
	Mean	SD	Mean	SD		
Weight (kg)	113.50	20.14	116.39	13.35	-0.498	0.618
Weight (kg)_At 1 month	106.36	18.69	111.10	12.58	-0.616	0.538
Weight (kg)_At 3 months	92.43	17.45	101.40	13.16	-1.406	0.160
Weight (kg)_At 6 months	83.64	15.80	93.00	13.72	-1.319	0.187
wgt 1m%	6.25	2.23	4.52	0.87	-1.670	0.095
wgt 3m%	18.50	5.87	12.83	5.57	-2.518	0.012
wgt 6m%	26.05	8.07	20.07	7.00	-2.225	0.026

Above table shows the comparison of weight in patient with diabetic remission score <8 and >8. It was observed that no difference was observed in the weight at different time interval (1month, 3 months and at 6 months). However, it was observed that percentage (loss) change in weight was significantly more in patients with DRS <8 at 3 months (18.50% vs 12.83%) and 6 months (26.05%vs 20.07).

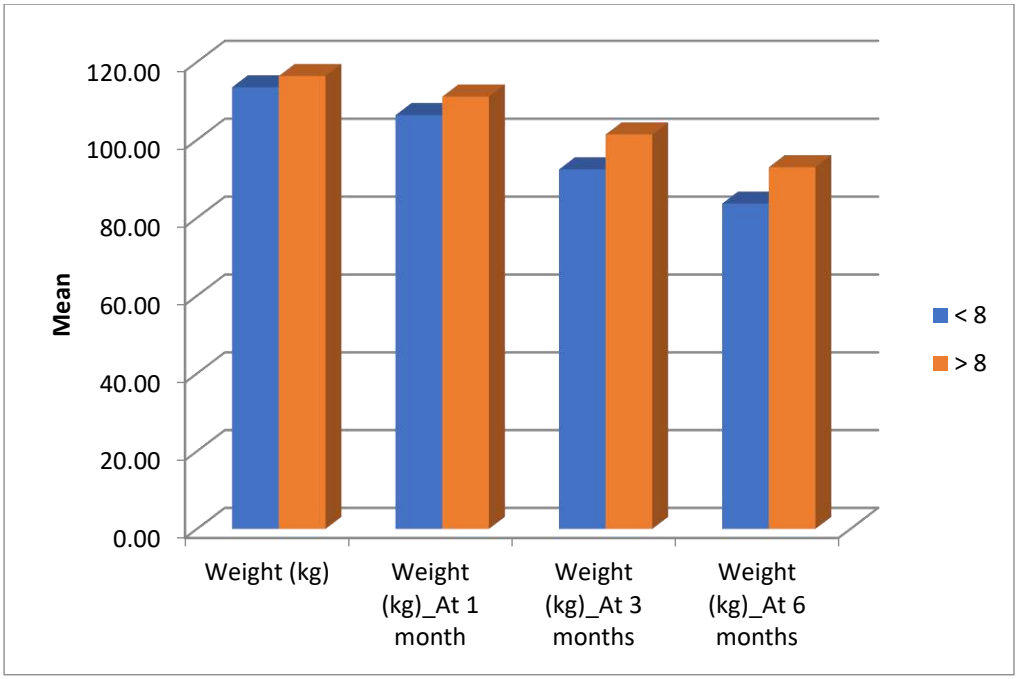

FIGURE 16A: COMPARISON OF MEAN WEIGHT ACCORDING TO DIABETES REMISSION SCORE (DRS)

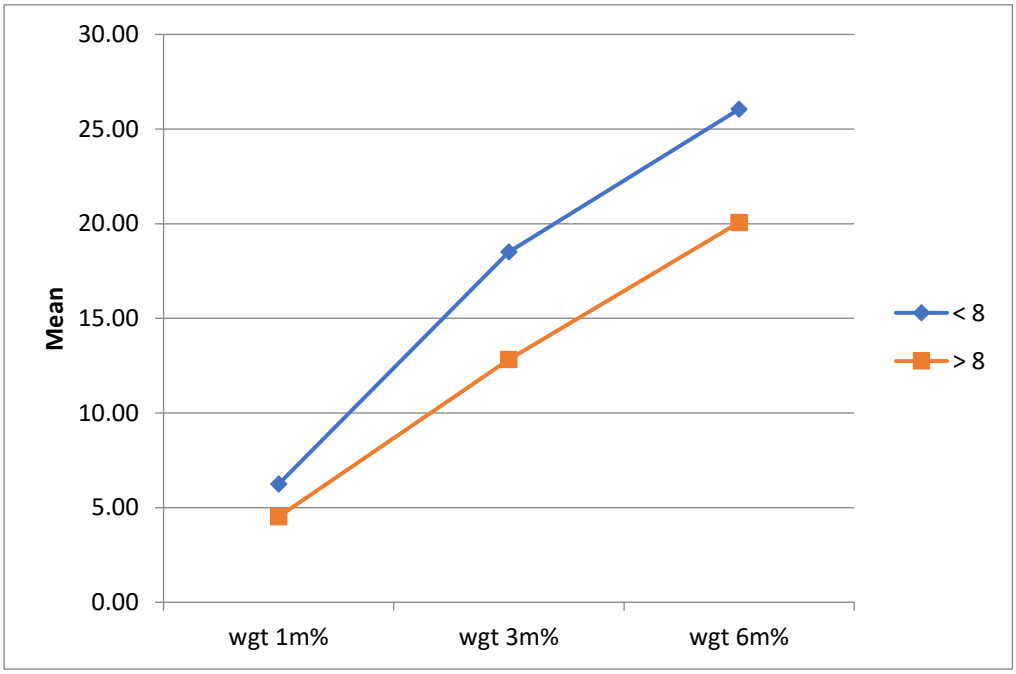

FIGURE 16B: COMPARISON OF MEAN WEIGHT % LOSS ACCORDING TO DIABETES REMISSION SCORE (DRS)

TABLE 21: COMPARISON OF MEAN BMI (KG/M2) ACCORDING TO DIABETES REMISSION SCORE (DRS)

Diabetes Remission Score	< 8		> 8		t	p-value
	Mean	SD	Mean	SD		
BMI (kg/m2)	43.65	6.62	44.19	6.83	-0.234	0.815
BMI (kg/m2)_At 1 month	40.90	6.04	41.51	6.06	-0.234	0.815
BMI (kg/m2)_At 3 months	35.40	4.76	36.21	5.06	-0.468	0.639
BMI (kg/m2)_At 6 months	32.02	4.34	32.10	3.85	-0.146	0.884
BMI 1m%	6.25	2.23	5.95	1.86	-0.351	0.725
BMI 3m%	18.50	5.87	17.61	6.78	-0.293	0.770
BMI 6m%	26.05	8.07	26.62	7.86	-0.059	0.953

Above table shows the comparison of BMI in patient with diabetic remission score <8 and >8. It was observed that no difference was observed in the BMI and %age loss in BMI at different time interval (1month,3 months and at 6 months).

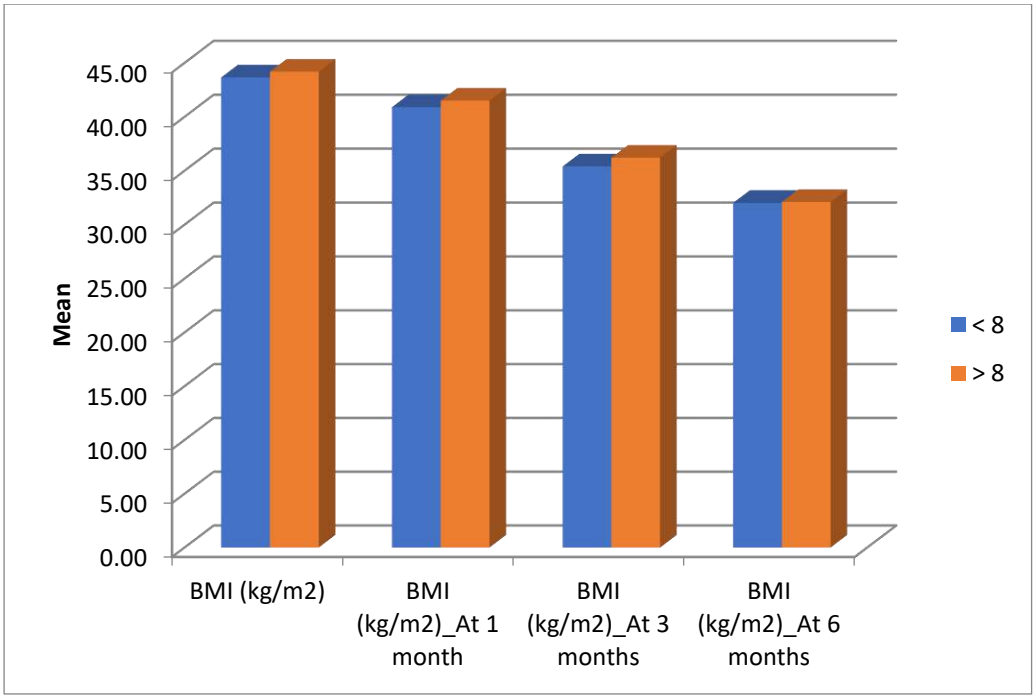

FIGURE 17A: COMPARISON OF MEAN BMI (kg/m2) ACCORDING TO DIABETES REMISSION SCORE(DRS)

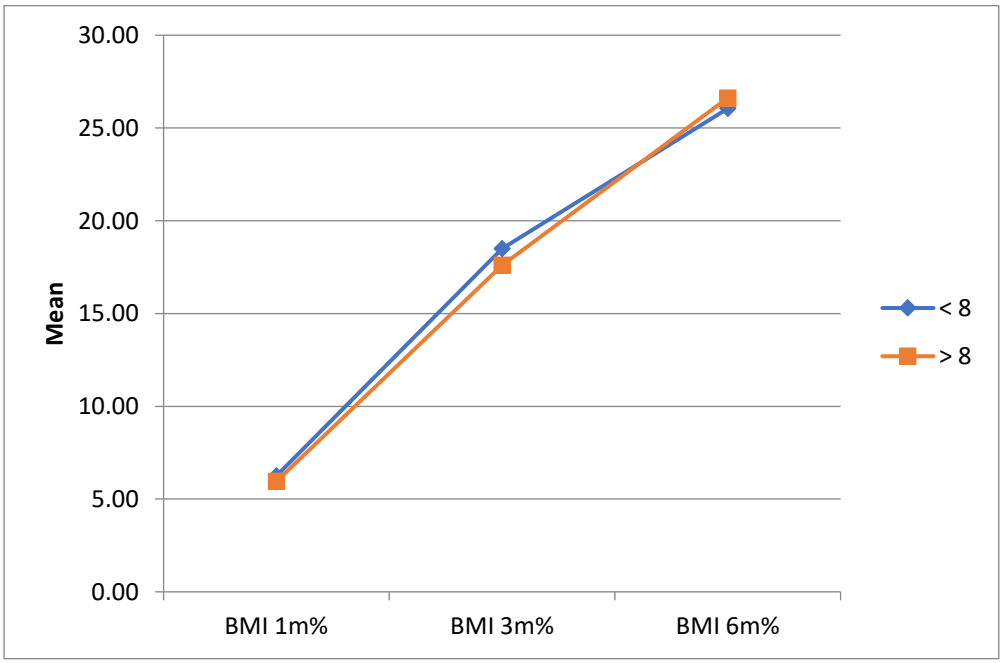

FIGURE 17B: COMPARISON OF MEAN BMI (kg/m2) % DECREASE ACCORDING TO DIABETES REMISSION SCORE(DRS)

TABLE 22: COMPARISON OF MEAN FBS (mg/dL) ACCORDING TO DIABETES REMISSION SCORE(DRS)

Diabetes Remission Score	< 8		> 8		t	p-value
	Mean	SD	Mean	SD		
FBS (mg/dL)	191.14	53.81	189.20	42.92	-0.264	0.792
FBS (mg/dL)_At 1 month	162.57	46.92	174.60	42.38	-1.288	0.198
FBS (mg/dL)_At 3 months	132.86	46.25	161.40	37.47	-1.933	0.053
FBS (mg/dL)_At 6 months	105.21	28.73	148.90	31.82	-3.221	0.001
FBS 1m%	14.92	4.92	7.84	3.03	-3.398	0.001
FBS 3m%	31.10	10.77	14.65	3.77	-3.837	<0.001
FBS 6m%	44.11	9.94	20.94	4.81	-4.099	<0.001

Above table shows the comparison of FBS in patient with diabetic remission score <8 and >8. It was observed that no difference was observed in the weight at different time interval (1month,3 months) however at 6 months highly significant difference was observed in two groups with FBS being significantly less in patients with DRS <8 (105.21±28.73 vs148.90±31.82). It was observed that percentage (loss) change in FBS was significantly more in patients with DRS <8 at 1 month (14.92±4.92% vs. 7.84±3.03%) 3 months (31.10%±10.77% vs. 14.65%±3.77%) and 6 months (44.11%±9.94%vs 20.94%±4.81%).

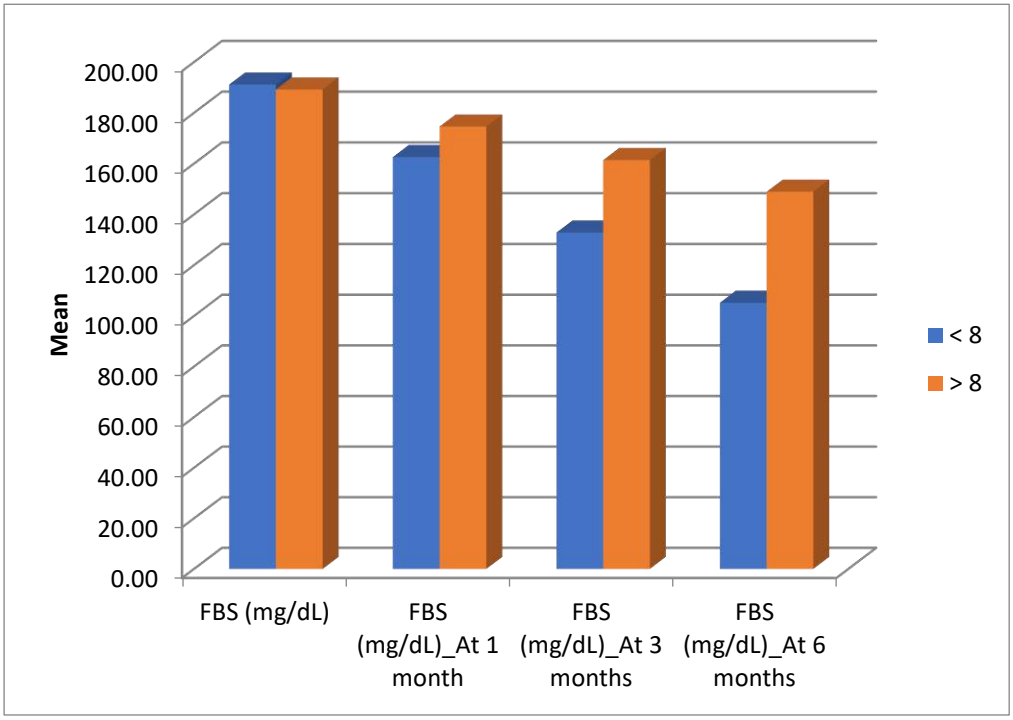

FIGURE 18A: COMPARISON OF MEAN FBS (mg/dL) ACCORDING TO DIABETES REMISSION SCORE(DRS)

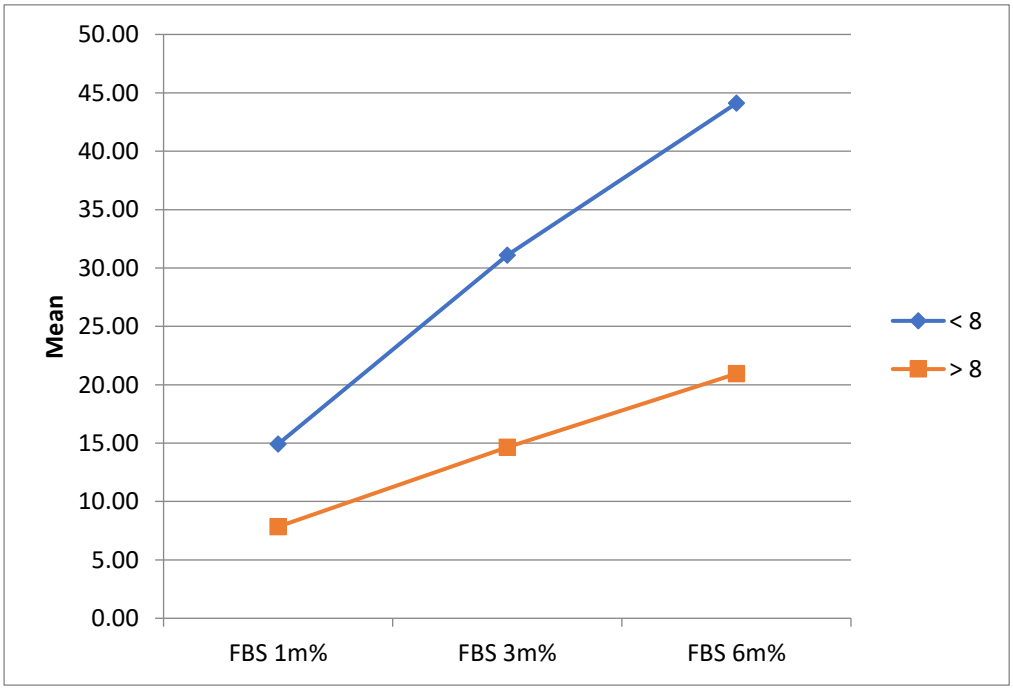

TABLE 18B: COMPARISON OF MEAN FBS (mg/dL) % DECREASE ACCORDING TO DIABETES REMISSION SCORE(DRS)

TABLE 23: COMPARISON OF MEAN HbA1c (%) ACCORDING TO DIABETES REMISSION SCORE(DRS)

Diabetes Remission Score	< 8		> 8		t	p-value
	Mean	SD	Mean	SD		
HbA1c (%)	8.07	1.34	8.12	1.57	0.000	1.000
HbA1c (%)_At 1 month	7.64	1.31	7.85	1.53	-0.323	0.747
HbA1c (%)_At 3 months	6.88	1.08	7.45	1.49	-1.322	0.186
HbA1c (%)_At 6 months	6.11	0.93	6.91	1.22	-2.258	0.024
HbA1c 1m%	5.46	2.16	3.33	0.62	-2.870	0.004
HbA1c 3m%	14.59	4.76	8.34	1.53	-3.045	0.002
HbA1c 6m%	24.03	5.27	14.69	14.69	-3.895	<0.001

Above table shows the comparison of HbA1c (%) in patient with diabetic remission score <8 and >8. It was observed that no difference was observed in HbA1c at 1month & 3 months, however at 6 months highly significant difference was observed in two groups with HbA1c (%) being significantly less in patients with DRS <8 (6.11±0.93 vs. 6.91 ±1.22). It was observed that percentage (decrease) change in HbA1c (%) was significantly more in patients with DRS <8 at 1 month (5.46% ±2.16% vs. 3.33%±0.62%) 3 months (14.59%±4.76% vs. 8.34%±1.53%) and 6 months (24.03%±5.27%vs 14.69%±14.69%).

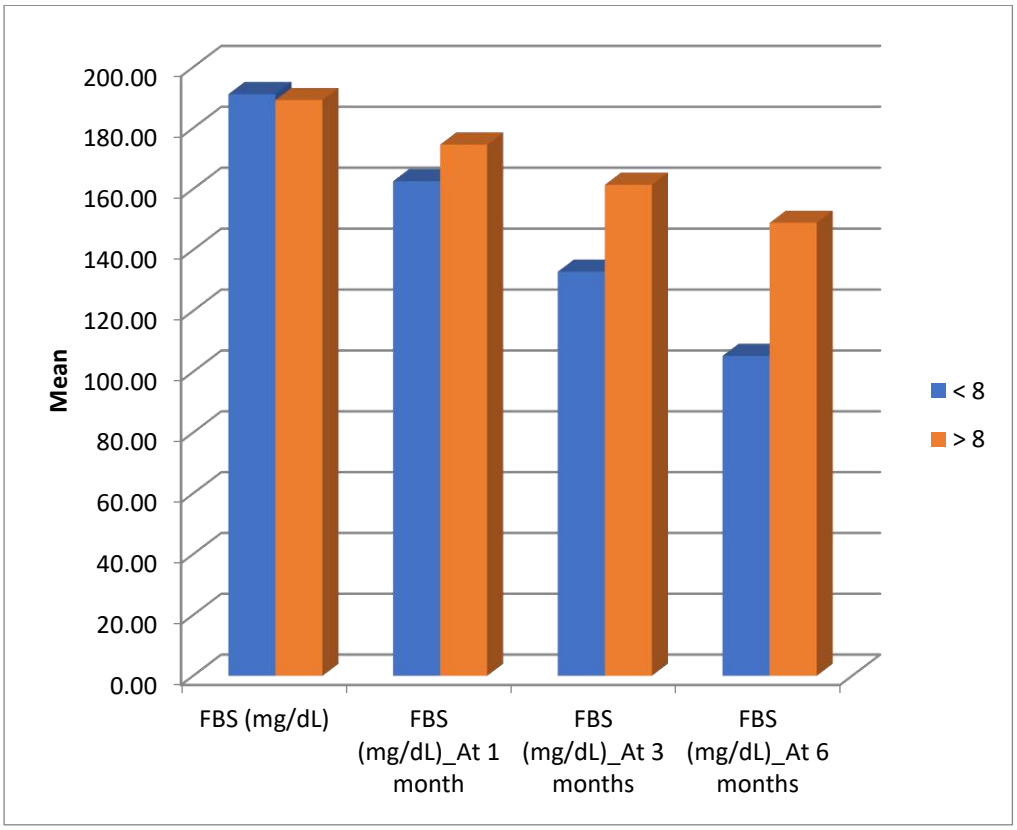

FIGURE 19A: COMPARISON OF MEAN HbA1c (%) ACCORDING TO DIABETES REMISSION SCORE(DRS)

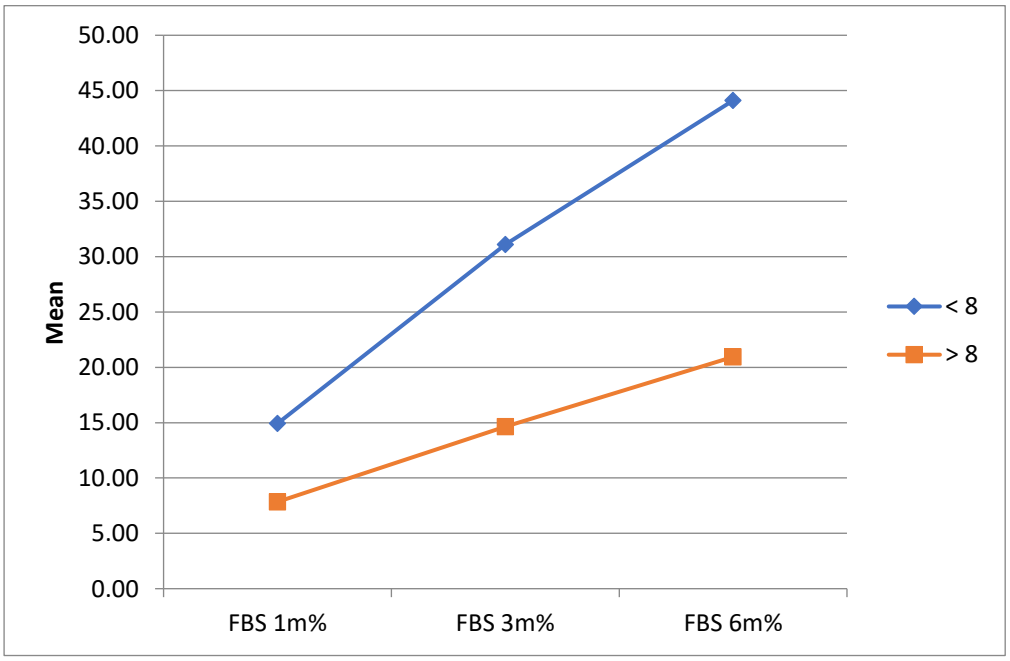

FIGURE 19B: COMPARISON OF MEAN HbA1c (%) % DECREASE ACCORDING TO DIABETES REMISSION SCORE(DRS)

TABLE 24: RELATIONSHIP OF OHA DOSE IN RESPECT TO DIABETES REMISSION SCORE(DRS)

		Diabetes Remission Score				Total	Chi-square value	p-value
		< 8		> 8				
OHA's dose_At 1 month		9	64.3%	5	50.0%	14	5.838	0.120
	1	2	14.3%	0	0.0%	2		
	2	3	21.4%	2	20.0%	5		
	4	0	0.0%	3	30.0%	3		
Total		14	100.0%	10	100.0%	24		
OHA's dose_At 3 months		13	92.9%	5	50.0%	18	9.143	0.027
	1	1	7.1%	0	0.0%	1		
	2	0	0.0%	2	20.0%	2		
	3	0	0.0%	3	30.0%	3		
Total		14	100.0%	10	100.0%	24		
OHA's dose_At 6 months		14	100.0%	5	50.0%	19	8.842	0.031
	1	0	0.0%	1	10.0%	1		
	2	0	0.0%	2	20.0%	2		
	3	0	0.0%	2	20.0%	2		
Total		14	100.0%	10	100.0%	24		

It was observed that no significant difference was observed in two groups at 1 month. However at 3rd month the usage of OHA decreases significantly in patients with DRS <8. At 6th month the usage was almost nil in patients with DRS <8.

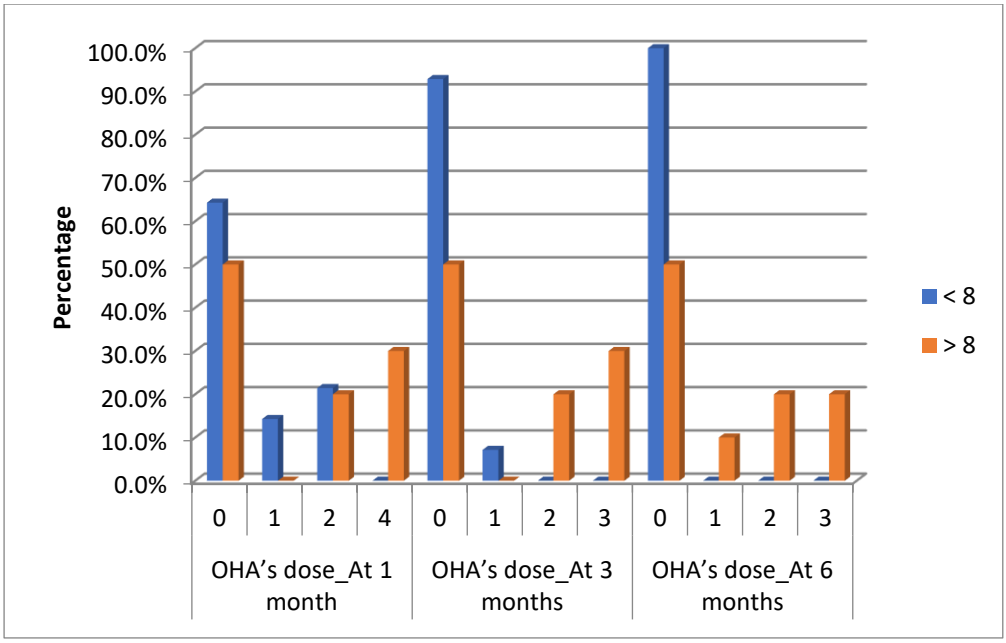

FIGURE 20: RELATIONSHIP OF OHA DOSE IN RESPECT TO DIABETES REMISSION SCORE(DRS)

TABLE 25: RELATIONSHIP OF INSULIN DOSE IN RESPECT TO DIABETES REMISSION SCORE(DRS)

		Diabetes Remission Score				Total	Chi-square value	p-value
		< 8		> 8				
Pre operative insulin use (total units)	No	9	64.3%	6	60.0%	15	0.046	0.831
	Yes	5	35.7%	4	40.0%	9		
Insulin dose_At 1 month	No	9	64.3%	7	70.0%	16	0.086	0.869
	Yes	5	35.7%	3	30.0%	8		
Insulin dose_At 3 months	No	10	71.4%	7	70.0%	17	0.006	0.939
	Yes	4	28.6%	3	30.0%	7		
Insulin dose_At 6 months	No	11	78.6%	7	70.0%	18	0.229	0.633
	Yes	3	21.4%	3	30.0%	6		
Total		14	100.0%	10	100.0%	24		

No significant difference was observed between insulin dose preoperatively and at 1 month,3 months and 6 months in patients with relation to DRS Score <8 and >8.

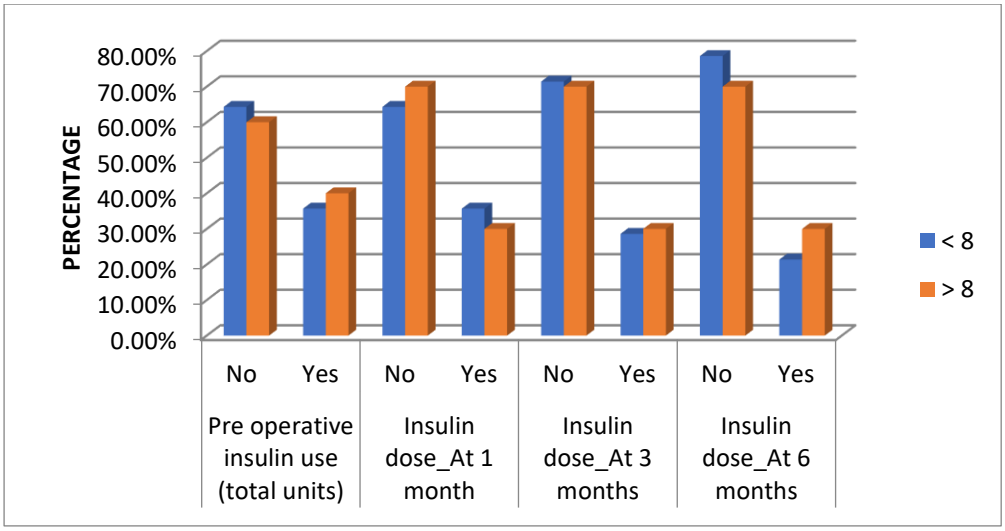

FIGURE 21: RELATIONSHIP OF INSULIN DOSE IN RESPECT TO DIABETES REMISSION SCORE(DRS)

RECEIVER OPERATING CHARACTERISTIC CURVES

A) In patients with complete remission

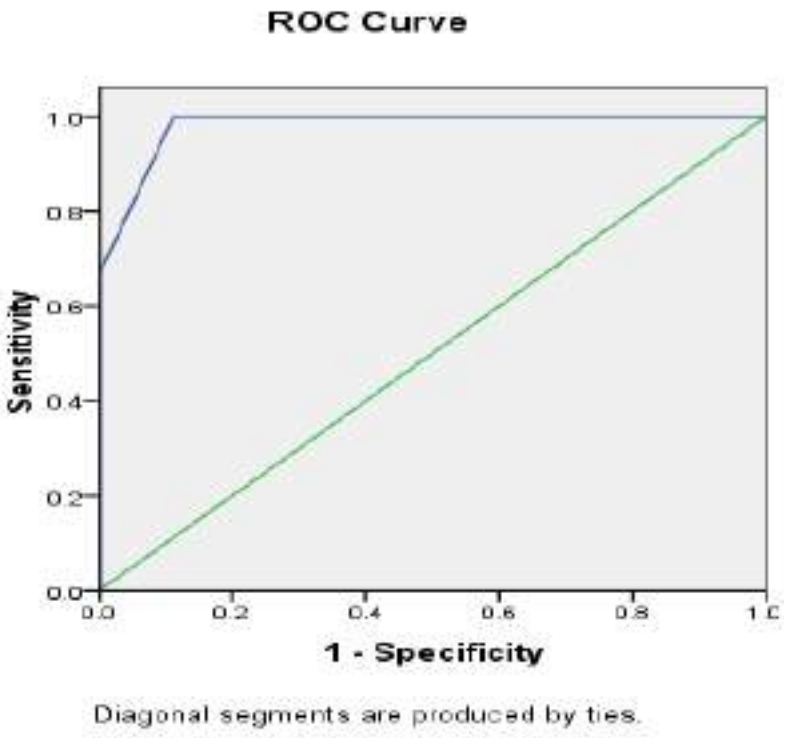

FIGURE 22: RECEIVER OPERATING CHARACTERISTIC CURVES FOR DRS TO ASSESS DIABETIC REMISSION

TABLE 26: AREA UNDER THE CURVE IN PATIENTS WITH COMPLETE REMISSION

Area Under the Curve				
Test Result Variable(s): DRS for diabetic remission				
Area under curve	Std. Error[a]	Asymptotic Sig.[b] p value	Asymptotic 95% Confidence Interval	
			Lower Bound	Upper Bound
0.981	0.024	0.000	0.000	1.000

We observed that area under the ROC curve for DRS score to assess complete diabetic remission is approximately 0.981 indicating that DRS score can be used as a simple tool for determining the presence of remission of diabetes in bariatic patients. Considering the entire cohort of patients, the accuracy (area under the ROC curve or c-index) for DRS for the assessment of the complete diabetic remission was .981 (standard error 0.024, 95% CI 0.0–1).

TABLE 27: SENSITIVITY SPECIFICITY OF CUT OFF VALUE

Cut-off	Sensitivity (%)	Specificity (%)	Positive Predictive Value (%)	Negative Predictive Value (%)	Accuracy (%)
7.5 (rounded off to 8)	100	90	64.29	100.00	79.17

Above shows the specificity, sensitivity at different cut-offs. It shows that the accuracy at cut-off 8 is highest out of all the predicted ratios.

TABLE 28: REMISSION OF DIABETES IN BOTH SCORING GROUPS

		Remission		Total	Chi-square value	p-value
		HBA1c <6	HBA1c >6			
Diabetes Remission Score group	<= 8	9	5	14	7.7	0.005
	> 8	0	10	10		
Total		9	15	24		

It is observed that at cut-off value of 8 for DRS score, 9 patients showed HBA1c level <6 i.e complete remission while in 5 patients, HbA1c level was >6. Similarly in patients with DRS score >8 it was observed that none of the patient showed HBA1c level ≤ 6, while 15 patients showed HBA1c level >6. This association was statistically significant which implies that DRS score can be used for assessment of diabetic remission in patients who underwent mini gastric bypass.

DISCUSSION

Type 2 diabetes mellitus (T2DM) is an increasing pandemic affecting >400 million people worldwide.[55] Unfortunately, approximately one third of these diabetes patients live in the Asia-Pacific area. The risk of developing T2DM is greater for obese Asians than for Caucasians with the same body mass index (BMI) because of the higher proportion of body fat and prominent abdominal obesity.[56-57]

Bariatric surgery is the most effective treatment for morbid obesity and has been proven successful in treating concomitant T2DM in morbidly obese patients (BMI > 35 kg/m 2) [58-59]. Recently, bariatric surgery, especially the gastric bypass surgery, has been accepted as a treatment modality in combination with lifestyle change and medical therapy for T2DM in mildly obese patients with a BMI < 35 kg/m 2 and insufficient glycemic control [60-61]

In present study 24 patients who underwent mini gastric bypass were assessed for diabetes remission at 1 month, 3 months and 6 months. Maximum patients who underwent surgery were <40 (41.7%) years of age, followed by patients in 50-60(29.2%) years, 41-50 years (20.8%) and least patients were present in age group >60years (8.3%) years. The mean age of the patients was 46.33± 9.49 years. In a study by Tinoco et al.[40] (2011) an average age of patients was 49.7 ± 8.9 years. Ahuja et al. [62] in their study reported the mean age was 45.63 ± 11.12 years. Lee et al. [63] in their study observed the mean age to be 44.2 ± 10.4 years (range 18–70 years). All the above studies were in accordance to the present study

In present study 54.2% patients were females while 45.8% patients were males. Lee et al. [63] 61.22% patients were females this was in accordance to the present study. In a study by Tinoco et al.[40] (n=30) 33.3% patients were females while 66.7% were males, Ugale et al. [21] also observed male predominance in their study this was in discordance to the present study.

Maximum patients in present study had Hypertension (HTN) alone (25%) followed by HTN with Obstructive sleep apnea (OSA) (8.3%)

and HTN with CAD (4.2%). Guh et al. in their meta analysis on obese patients reported that both overweight and obesity are associated with the incidence of multiple co-morbidities including type II diabetes, cancer and cardiovascular diseases.[64] Jensen et al. in their review reported that patients with obesity are at increased risk of morbidity from dyslipidemia, T2DM, hypertension, coronary artery disease, stroke, gallbladder disease, respiratory problems, sleep apnea, osteoarthritis, and some cancers.[20] Mokdad et al. reported that compared with adults of normal weight, adults with a BMI of 40 kg/m2 or higher had an increased risk of diabetes, hypertension, hyperlipidemia, asthma, and fair or poor health.[65] These studies were in accordance to the present study as in present study all the patients were reported to have diabetes, followed by hypertension, OSA and CAD.

In 45.8% patients in the study showed the presence of microvascular complications while macrovascular complications were observed in 33.33 % patients

The mean BMI of the patients in the present study was 43.88±6.56. Ahuja et al.[62] in their study reported the mean BMI to be 44.85 ± 9.24 kg/m2. In a study by Sohal et al.[54] the mean BMI was 45.24 ± 7.26. These studies were in accordance to the present study. In contrast to the present study Lee et al.[63] reported the mean BMI in their study to be 35.7 (7.8). C-Peptide (ng/ml) in present study was 5.29±2.90 Sohal et al.[54] and Lee et al.[63] in their study reported the mean C peptide to be 4.86 ± 2.30, and 3.6 (2.0) respectively. The preoperative insulin dosage in the present study was 30.44±11.35 units. Similar results were obtained by Sohal et al.[54] who observed 32.86 ± 12.44 units of insulin requirement. Lee et al.[63] in their study observed the mean insulin requirement by the patients to be 26.1.

On comparing various observed variables after surgery it was observed that significant change was observed in weight, BMI, OHA requirement, FBS, HBA1c preoperatively and after surgery.

It was observed that on comparing weight of the patients preoperatively (114.70±17.35) and at 1 month, 3 months and 6 months

the weight was significantly less at 1 month (108.33±16.28), 3 month (96.17±16.13) and 6 month (87.54±15.39) (p<.001).

On comparing BMI of the patients preoperatively (43.88±6.56) and at 1 month, 3 months and 6 months it was observed that the BMI was significantly less at 1 month (41.15±5.92), 3 months (35.74±4.79) and 6 months (32.05±4.05) (p<.001).

Also reduction in OHA dose and insulin dose was observed preoperatively and postoperatively.

Tinoco et al.[40] in their study observed similar findings . in their study patients were followed for a period of 6–18 months (average 13 ± 3.3 months) after surgery. All 30 patients evolved with weight loss: i.e., the BMI values of the patients prior to and after surgery were significantly different (P = 0.0001) as determined by paired t tests. Ahuja et al.[62] in their study showed that after 1 year of surgery, the mean percent excess body weight loss was 64.46 ± 19.39, mean weight decreased from 115.83 ± 25.64 kg to 82.21 ± 16.80 kg (p < 0.05), BMI decreased from 44.85 ± 9.24 to 31.65 ± 5.98 kg/m2 (p < 0.05). Musella et al. [50] in their study reported that after mini gastric bypass (MGB) the BMI decreased from 48.3±9.2 to 33.1±6.6, p<0.001; these studies were in accordance to the present study.

On comparing FBS of the patients preoperatively (190.33±48.56) and at 1 month, 3 months and 6 months it was significantly less at 1 month (167.58±44.54), 3 months (144.75±44.33) and 6 months (123.42±36.70). Similarly when HbA1c (%) of the patients was compared preoperatively (8.09±1.41) and at 1 month, 3 months and 6 months, it was significantly less at 1 month (7.73±1.38), 3 months (7.12±1.27) and 6 months (6.44±1.11) (p<.001).

In a study by Tinoco et al.[40] the mean postsurgical blood levels of HbA1c, fasting glucose, were significantly lower (P = 0.0001, 0.0001 respectively) than those determined prior to surgery. Sohal et al.[54]reported significant improvement in FBS from 193.05 preoperatively to 136.95 at 3 months and 107.97 at 6 months, in HbA1C from 8.22 preoperatively to 7.01 at 3 months and 6.17 at 6 months, and in BMI from 45.24 preoperatively to 36.26 at 3months and

32.56 at 6 months. The dose of OHAs and insulin was also reduced significantly. Ahuja et al.[62] in their study showed that mean HbA1C decreased from 8.26 ± 1.8 to 5.96 ± 0.89 ($p < 0.05$). These studies were in favour of the present study.

Different metabolic surgical procedures show different result in the rate of resolution of T2DM and co-morbidities. A perfect scoring system for predicting T2DM remission will assist the metabolic surgery team not only in proper selection of the patients but also in selecting the type of procedure to be performed. Our study focuses on the development of a relatively novel score (DRS) preoperatively in predicting diabetes remission following mini gastric bypass. DRS was derived from the variable factors predicting the remission in diabetes. Ugale et al.[21]. used this score for predicting the remission in patients with T2DM undergoing ileal interposition with sleeve gastrectomy (IISG) or ileal interposition with diverted sleeve gastrectomy (IIDSG)[i]. Seven variables, age, BMI, duration of T2DM, microvascular complications (retinopathy, nephropathy, etc.), macrovacular complications like CAD, preoperative insulin use, and stimulated C-peptide, were included.

Each of these seven variables was scored by a two-point scoring system. The score ranges from 7 to 12. Lower scores indicate a higher probability of achieving remission after surgery. According to this the study cohort was divided in to 2 groups <=8 and >8. 14 patients in present study had score <=8 while 10 patients had score ≤8 it was observed that percentage (loss) change in weight was significantly more in patients with DRS ≤8 than >8 at 3 months (18.50% vs 12.83%) and 6 months (26.05%vs 20.07%). However, on comparing BMI in the two groups It was observed that no difference was observed at different time interval (1month,3 month and at 6 month).

The role of BMI as a predictor of T2DM remission has been controversial. Robert et al. [66] in their study have shown that a BMI < 35 is a positive predictor for T2DM remission, whereas Dixon et al. showed an opposite of this result, BMI > 35 being a positive predictor [67]. Wang et al. found that baseline BMI played a role in T2DM

remission only in Asian population [68], while some studies have shown no relation of baseline BMI with remission of T2DM [69-71]

On comparing FBS in patient with diabetic remission score ≤8 and >8, it was observed that no difference was observed in the FBS at different time interval (1month,3 months) however at 6 months highly significant difference was observed in two groups with FBS being significantly less in patients with DRS ≤8 (105.21±28.73 vs 148.90±31.82). It was observed that percentage (loss) change in FBS was significantly more in patients with DRS ≤8 at 1 month (14.92±4.92% vs. 7.84±3.03%) 3 months (31.10%±10.77% vs. 14.65%±3.77%) and 6 months (44.11%±9.94% vs 20.94%±4.81%).

It was observed that no difference was observed in HbA1c at 1month & 3 months, however at 6 months highly significant difference was observed in two groups with HbA1c (%) being significantly less in patients with DRS ≤8 (6.11±0.93 vs. 6.91 ±1.22). It was observed that percentage (decrease) change in HbA1c (%) was significantly more in patients with DRS ≤8 at 1 month (5.46% ±2.16% vs. 3.33%±0.62%) 3 month (14.59%±4.76% vs. 8.34%±1.53%) and 6 months (24.03%±5.27%vs 14.69%±14.69%).

It was observed that at 3rd month the usage of OHA decreases significantly in patients with DRS ≤8. At 6th month the usage was almost nil in patients with DRS ≤8. However, no significant difference was observed between insulin dose preoperatively and at 1 month,3 month and 6 month in patients with relation to DRS Score ≤8 and >8.

In our study, we have assessed the diabetic remission with DRS scores with the help of ROC curve. The AUC gave us the sensitivity and specificity of DRS scoring system for predicting the remission of T2DM. On applying ROC curve, it was noted that, DRS score of < 8 had the maximum AUC of 0.98 and best sensitivity and specificity to predict the remission of T2DM, i.e., 100% and 66.7%.

Ahuja et al.[62] in their study compared 3 scores and found that on applying ROC, DiaRem score of < 8 had the maximum AUC of 0.844 and best sensitivity and specificity to predict the remission of T2DM, i.e., 91.7 and 66.7%. The AUC for ABCD score > 4 was 0.769 with

sensitivity and specificity of 90.3 and 56.7%, respectively, while AUC for DRS was 0.804 with sensitivity and specificity of 88.9 and 60%, respectively. In their study though Diarem had maximum AUC, the pair-wise comparison of these three scores did not show a statistically significant difference. This result could be because in all three algorithms, some of the factors represented the beta cell reserve directly or indirectly.

It is observed that at cut-off value of 8 for DRS score 9 patients showed HBA1c level <6 while in 5 patients HbA1c level was >6. Similarly in patients with DRS score >8 it was observed that none of the patient showed HBA1c level ≤ 6, while 15 patients showed HBA1c level >6. This association was statistically significant which implies that DRS score can be used for assessment of diabetic remission in patients who underwent bariatic surgery.

DRS was significantly lower in patients with remission than patients without remission. This demonstrates that patients with lower baseline DRS have better remission rates. However, our data also demonstrate that DRS was however higher in non-remission group still there was a decrease in FBS, HBA1c and OHA use in patients with DRS<8 suggesting the benefits of bariatic surgery. However, DRS is a relatively newer scoring system for predicting the diabetic remission rate therefore limited comparative studies were available to support present results.

Diabetes remission score is a useful tool for predicting the remission in patients with type 2 diabetes undergoing mini gastric bypass. We propose that DRS as a simple tool to predict the postoperative diabetes remission. Further multicenter studies of patients from various ethnicities are required to confirm our preliminary observations.

SUMMARY AND CONCLUSION

DRS score was calculated for 24 morbidly obese diabetic patients who underwent mini gastric bypass at out institution over 1 year and follow up was done for 6 months after surgery. Following conclusion was drawn:

- Mini gastric bypass resulted in significant weight loss and reduction in BMI in patients at 1 month, 3 months and 6 months.
- There occurred a significant improvement in FBS and significant improvement was seen in HBA1c following surgery. Also there was reduction in insulin dose and OHA usage after 6 months.
- Complete remission of diabetes occurred in 58.3% of patients at 6 months.
- DRS score of >8 was significantly associated with decreased diabetic remission. The cut off of ≤8 was calculated using ROC for predicting the diabetes remission
- It was observed that though the improvement in HBA1c, FBS, BMI, weight loss was more in remission group but the non-remission group also showed improvement which was less than the remission group.

Thus, we conclude that mini gastric bypass leads to the substantial weight loss and amelioration of type 2 diabetes. Diabetes remission score is a useful tool for predicting the remission in patients with type 2 diabetes undergoing mini gastric bypass. We propose that DRS as a simple tool to predict the postoperative diabetes remission. Further multicenter studies of patients from various ethnicities are required to confirm our preliminary observations.

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Sr. No	MRD No	Name	Age	Sex	Date	History of presenting complaints	Comorbidities	OHA (PREOP)	Duration of type 2 diabetes mellitus	Presence of clinical microvascular complications	Pre operative insulin use (total units)	Presence of clinical macrovascular complications	GPE			INVESTIGATIONS		
													Height (m)	Weight (kg)	BMI (kg/m2)	FBS (mg/dL)	HbA1c (%)	C-Peptide (ng/ml)
1	760282	HK	54	F	Jan-20	MORBID OBESITY	DM-2 , HTN	3	11	YES	-	YES	1.7	115	39.7923	192	8.2	5.26
2	719448	JS	38	M	Jan-20	MORBID OBESITY	DM-2	1	2	NO	-	NO	1.6	90	35.1563	171	7.3	6.8
3	759333	SS	43	M	Jan-20	MORBID OBESITY	DM-2	2	4	YES	-	NO	1.7	123	42.5606	162	7	9.72
4	182910	HS	44	F	Jan-20	MORBID OBESITY	DM-2	1	3	NO	-	NO	1.55	139	57.8563	144	6.9	6.03
5	812053	JP	58	M	Feb-20	MORBID OBESITY	DM-2 , HTN , OSA	1	13	YES	-	YES	1.6	132.9	51.914	158	7.1	3.75
6	505192	AG	39	M	Feb-20	MORBID OBESITY	DM-2	-	1	NO	26	NO	1.64	134	49.8215	176	7.5	10.5
7	851443	NQ	40	F	Feb-20	MORBID OBESITY	DM-2	-	1	NO	42	NO	1.54	95	40.0573	260	9.9	1.1
8	852433	RS	51	F	Feb-20	MORBID OBESITY	DM-2 , HTN	-	11	YES	18	YES	1.68	108	38.2653	190	8	4.2
9	867708	GG	38	M	Mar-20	MORBID OBESITY	DM-2	4	0.7	NO	-	NO	1.57	98	39.7582	201	8.5	6.93
10	814213	NJ	38	F	Oct-20	MORBID OBESITY	DM-2	-	0.5	NO	42	NO	1.625	100	37.8698	280	10	1.32
11	651112	AA	40	F	Oct-20	MORBID OBESITY	DM-2	2	2.5	NO	-	NO	1.57	98	39.7582	147	6.9	3.22
12	900644	IK	51	F	Oct-20	MORBID OBESITY	DM-2 , HTN	2	7	YES	-	YES	1.55	114	47.4505	176	7.3	7.47
13	679675	KK	61	M	Oct-20	MORBID OBESITY	DM-2 , HTN , OSA	1	18	YES	-	YES	1.76	132	42.6136	160	7.2	5.5
14	927968	AK	53	F	Nov-20	MORBID OBESITY	DM-2 , HTN	1	14	YES	-	YES	1.57	87	35.2955	158	7	5.2
15	971787	PA	46	F	Nov-20	MORBID OBESITY	DM-2	-	8	YES	12	NO	1.5	127	56.4444	147	6.9	11
16	980743	HK	54	M	Nov-20	MORBID OBESITY	DM-2 , HTN	5	15	YES	-	YES	1.8	120	37.037	195	8	3.9
17	993257	YG	36	F	Nov-20	MORBID OBESITY	DM-2	-	1.5	NO	46	NO	1.5	100	44.4444	310	11	2.87
18	1000138	SK	38	M	Dec-20	MORBID OBESITY	DM-2	1	2.5	NO	-	NO	1.84	146	43.1238	152	7.6	9.58
19	8272	PD	36	M	Dec-20	MORBID OBESITY	DM-2	1	2	NO	-	NO	1.9	144	39.8891	144	7	7.6
20	1083423	SS	45	F	Dec-20	MORBID OBESITY	DM-2	-	3	NO	30	NO	1.6	120	46.875	197	8.6	3.4
21	752727	NK	45	F	Dec-20	MORBID OBESITY	DM-2	2	6	NO	-	NO	1.58	97	38.8559	172	7.6	4.9
22	743901	SS	38	M	Jan-21	MORBID OBESITY	DM-2	2	2	NO	-	NO	1.38	105	55.1354	160	7.2	2.1
23	36331	OP	74	M	Jan-21	MORBID OBESITY	DM-2 , HTN , CAD	4	26	YES	30	YES	1.56	112	46.0223	224	9.5	2.7
24	704663	AR	52	F	Jan-21	MORBID OBESITY	DM-2 , HTN	4	15	YES	28	NO	1.57	116	47.0607	292	12	2

Sr. No	MRD No	Diabetes Remission Score	Weight (kg)			BMI (kg/m2)			FBS (mg/dL)			HbA1c (%)			Insulin dose			OHA's dose		
			At 1 month	At 3 months	At 6 months	At 1 month	At 3 months	At 6 months	At 1 month	At 3 months	At 6 months	At 1 month	At 3 months	At 6 months	At 1 month	At 3 months	At 6 months	At 1 month	At 3 months	At 6 months
1	760282	10	110	100	86	38.0622	34.602	29.7577	165	150	135	8	7.6	7.1	-	-	-	2	2	2
2	719448	7	85	79	76	33.2031	30.8593	29.6875	142	96	80	6.9	6.2	5.6	-	-	-	-	-	-
3	759333	8	118	104	98	40.8304	35.9861	33.91	135	85	76	6.6	6.1	5.6	-	-	-	1	-	-
4	182910	7	130	115	102	54.1103	47.8668	42.4557	120	72	74	6.1	5.5	5.3	-	-	-	-	-	-
5	812053	10	127	120	100	49.6093	46.875	39.0625	145	135	128	6.8	6.4	6	-	-	-	-	-	-
6	505192	8	130	115	106	48.3343	42.7572	39.411	136	120	112	7.1	6.4	6.1	14	-	-	-	-	-
7	851443	8	92	76	68	38.7923	32.0458	28.6726	233	204	172	9.3	8.4	8.1	36	26	24	-	-	-
8	852433	11	100	86	78	35.4308	30.47	27.64	170	158	140	7.7	7.2	6.6	14	10	6	-	-	-
9	867708	7	94	83	78	38.1354	33.672	31.64	167	142	95	8	7.2	5.8	-	-	-	2	-	-
10	814213	8	96	89	85	36.35	33.704	32.189	212	170	110	9.4	8.2	6.9	36	18	9	-	-	-
11	651112	7	90	80	70	36.51	32.45	28.398	129	114	97	6.5	6	5.5	-	-	-	1	-	-
12	900644	9	105	93	86	43.704	38.709	35.796	158	145	138	7.1	6.6	6.2	-	-	-	2	2	1
13	679675	10	125	109	102	40.3538	35.188	32.928	150	137	128	6.9	6.5	6.1	-	-	-	-	-	-
14	927968	10	84	77	70	34.078	31.2385	28.398	148	135	129	6.8	6.4	6.1	-	-	-	-	-	-
15	971787	10	115	86	70	51.11	38.22	31.11	140	136	130	6.7	6.4	6	-	-	-	-	-	-
16	980743	10	112	100	95	34.567	30.864	29.32	180	168	154	7.7	7.4	6.9	-	-	-	4	3	3
17	993257	8	93	83	78	41.33	36.88	34.66	276	234	149	10.6	9.2	7.8	36	24	12	-	-	-
18	1000138	7	135	116	102	39.87	34.2627	30.127	126	95	72	7.1	5.8	5	-	-	-	-	-	-
19	8272	7	132	120	105	36.565	33.2409	29.0858	121	109	92	6.7	6.2	5.4	-	-	-	-	-	-
20	1083423	8	110	84	72	42.9687	32.812	28.125	176	166	121	8.2	7.2	6.7	22	12	-	-	-	-
21	752727	7	89	78	71	35.65	31.244	28.44	154	128	116	7.4	7.1	5.9	-	-	-	2	1	-
22	743901	7	95	72	60	49.8844	37.807	31.505	149	125	107	7	6.8	5.8	-	-	-	2	-	-
23	36331	12	106	98	89	43.556	40.2695	36.571	210	198	180	9.2	9	8.5	26	20	16	4	3	2
24	704663	10	110	88	75	44.626	35.7012	30.4271	280	252	227	11.6	11	9.6	24	20	16	4	3	3

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The Principal,
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Subject: **Approval of Plan of Thesis.**

This is to inform you that the Faculty of Medical Sciences in its meeting held on 22.01.2021 has approved the plan of thesis of **Dr. Shubhankar Matta,** a student of your college for **MS General Surgery** along with the names of Supervisor/Co-Supervisor as under:-

Topic Plan of Thesis
To study the outcome of type 2 diabetes mellitus in patients undergoing mini gastric bypass using diabetes remission score calculator

Supervisor
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The student has to submit the three copies of thesis (along with PDF format) , to the Controller of Examinations, BFUHS, Faridkot, at least six months before the commencement of theory examination, if he/she is otherwise eligible to take the examination. He /She must directed to attach a photocopy of this letter with the forwarding letter while submitting thesis to the University along with the letter of approval of University for change of supervisor/Co-Supervisor, change of topic,(if any).

Dr. S P Singh MS(Oph)
Controller of Examinations

Note :

1. ***If any discrepancy found regarding topic of thesis or Supervisor/Co-Supervisor, inform undersigned within one month after issue of this letter.***
2. *The student may submit the thesis as per the schedule already conveyed i.e for May/June examination 30th Nov of the preceding the year of examination and for Nov/Dec examinations 31st May of the year of examination.*

TO STUDY THE OUTCOME OF TYPE 2 DIABETES MELLITUS IN PATIENTS UNDERGOING MINI GASTRIC BYPASS USING DIABETES REMISSION SCORE CALCULATOR

THESIS PROPOSAL

FOR APPROVAL OF SUBJECT OF THESIS TO BE SUBMITTED

IN PARTIAL FULFILMENT OF THE REQUIREMENTS

FOR THE DEGREE OF

MASTER OF SURGERY

IN

GENERAL SURGERY

OF THE

BABA FARID UNIVERSITY OF HEALTH SCIENCES

FARIDKOT

NOVEMBER 2019

DR. SHUBHANKAR MATTA

DEPARTMENT OF GENERAL SURGERY
DAYANAND MEDICAL COLLEGE AND HOSPITAL
LUDHIANA

ABSTRACT OF PLAN OF THESIS

Title	TO STUDY THE OUTCOME OF TYPE 2 DIABETES MELLITUS IN PATIENTS UNDERGOING MINI GASTRIC BYPASS USING DIABETES REMISSION SCORE CALCULATOR
For the degree of	Master of Surgery
Name of the candidate	Dr. Shubhankar Matta
Supervisor	Dr. Prabhdeep Singh Nain, Professor, Department of General Surgery, DMCH, Ludhiana
Co-supervisors	Dr. Ashish Ahuja , Professor, Department of General Surgery, DMCH, Ludhiana Dr. Parminder Singh, Professor & Head, Department of Endocrinology, DMCH, Ludhiana.
Institution	Dayanand Medical College & Hospital, Ludhiana
University	Baba Farid University of Health Sciences, Faridkot

Introduction: Bariatric surgery is recommended as a treatment option in patients with type-2 DM and BMI > 35 kg/m2. However , remission of diabetes following bariatric surgery has varied from 24-73% in various studies. This scoring system aims to pre operatively predict the remission of type-2 DM following Mini Gastric Bypass, Type of Bariatric Surgery.

Aim of the study: 1.To study the outcome of type 2 diabetes mellitus in patients undergoing mini gastric bypass. 2. To evaluate the possibility of using diabetes remission score calculator to help with patient selection

Materials and methods: It will be a time bound prospective observational study over period of one year of patients undergoing Mini Gastric Bypass with Type 2 Diabetes Mellitus & followed up at 1 , 3 & 6 months after surgery for control/remission of type 2 DM

Clinical significance: This study evaluates the diabetes remission score calculator as a predictor of control of type 2 diabetes mellitus in patients undergoing bariatric surgery and whether it can be used to aid patient selection.

Keywords: diabetes, obesity, BMI, bariatric surgery, mini gastric bypass

(Signature)	(Signature)	(Signature)	(Signature)	(Signature)
Candidate	Co-supervisor	Co-supervisor	Supervisor	Principal

CERTIFICATE OF FACILITIES AVAILABLE

This is to certify that the facilities for work on the subject of thesis titled **"TO STUDY THE OUTCOME OF TYPE 2 DIABETES MELLITUS IN PATIENTS UNDERGOING MINI GASTRIC BYPASS USING DIABETES REMISSION SCORE CALCULATOR"** exist in the Department of General Surgery, DMC&H, Ludhiana and will be provided to be candidate. We will see that the data being included in the thesis are genuine and is collected by the candidate himself/herself under our supervision and guidance.

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APPROVAL PROFORMA

BY RESEARCH & ETHICAL COMMITTEE

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Department	SURGERY
Topic of Thesis	TO STUDY THE OUTCOME OF TYPE 2 DIABETES MELLITUS IN PATIENTS UNDERGOING MINI GASTRIC BYPASS USING DIABETES REMISSION SCORE CALCULATOR
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PROFORMA FOR REGISTRATION OF SUBJECT FOR DISSERTATION

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4	DATE OF ADMISSION OF COURSE	04.05.2019
5	TITLE OF THE TOPIC	TO STUDY THE OUTCOME OF TYPE 2 DIABETES MELLITUS IN PATIENTS UNDERGOING MINI GASTRIC BYPASS USING DIABETES REMISSION SCORE CALCULATOR

6. BRIEF RESUME OF THE INTENDED WORK

6.1 NEED FOR THE STUDY

Economic development in India has led to a shift in disease burden, with a huge increase in non-communicable disease. The prevalence of obesity, for example, has risen even in rural areas. Some 42% of the population in rural Kerala have been reported to be either overweight or obese.[1] A study of an urban slum in northern India reported 40% of the women to be obese,[2] and the prevalence of obesity among 350 patients attending a clinic for diabetes mellitus in Gujarat was 70%.[3]

Bariatric surgery is seen as a tool for tackling obesity. Some studies suggest that bariatric surgery could even help to prevent diabetes mellitus, especially in patients who are obese.[4]

Patients with diabetes often find it difficult to cope with multiple insulin injections. They can feel frustrated when their glycaemic control remains poor despite their best efforts. Their quality of life can decline,[5] and a vicious cycle of non-adherence to treatment and poor glycaemic control can set in. The quality of life of obese patients undergoing bariatric surgery is thought to improve as a result of weight loss and many patients perceive bariatric surgery to be a panacea.[6]

The number of patients in India undergoing bariatric surgery is rising. The Obesity Surgery Society of India has stated that the number of people having such surgery rose from 2200 in 2010 to more than 5000 in 2011.[7]

Bariatric surgery has evolved from a surgical measure for treating morbid obesity to an epochal remedy for treating metabolic syndrome as a whole, which is represented by type 2 diabetes mellitus. Numerous clinical trials have advocated bariatric or metabolic surgery over nonsurgical interventions because of markedly superior metabolic outcomes in morbidly obese patients who satisfy traditional criteria for bariatric surgery (body mass index [BMI] >35 kg/m^2) and in less obese or simply overweight patients.[8]

Bariatric surgery has proved to be a useful tool in control/remission of type 2 diabetes mellitus. American heart association/ American college of cardiology guidelines recommend conservative therapy for those

with BMI >30 or BMI between 25-29.99 with obesity related comorbidities. They recommend bariatric surgery for those with BMI greater than 40kg/m^2 Or a BMI greater than 35kb/m^2 with an associated comorbid medical problem and failure to achieve weight loss by dietary and behavioral therapy.[9]

Mini gastric bypass is becoming more and more popular , especially in India, and has proven to be a safe and effective alternative to other bariatric procedures with less mortality and post op complications. Not many studies have been done to evaluate the outcome of diabetes mellitus type 2 after mini gastric bypass. This study aims to study the outcome of type 2 diabetes mellitus after mini gastric bypass using a relatively new scoring system which is the Diabetes Remission Scoring System (DRSS). Other scoring system have been used to study the outcome of type 2 diabetes mellitus in the past such as the ABCD system and the DiaRem scoring system. The DRSS can prove to be superior to these as it also takes into account pre operative insulin use and presence or absence of micro/macro vascular complications , in its criteria. Earlier the Diabetes Remission Score (DRS) has been used in patients undergoing Ileal Interposition coupled with Sleeve Gastrectomy (IISG) or Diverted Sleeve Gastrectomy (IIDSG). In this study we will specifically apply the DRSS in patients who are about to undergo Mini Gastric Bypass procedure and evaluate the outcome of type 2 diabetes mellitus at follow up.

6.2 REVIEW OF LITERATURE

In a study conducted in 75 patients by Surendra Ugale et al, it was concluded that twenty one (46%) had a remission in diabetes. Diabetes remission score (DRS) was significantly lower in patients with remission than patients without remission thus proving that preoperative DRS can be a useful tool to select the type of surgical procedure and to predict the postoperative diabetes remission.[10]

Christopher d still et al, conducted a study in 690 patients in 2013 using the DiaRem score calculator to predict the remission of type 2 DM after RYGB and found that 63% achieved partial / complete remission.[11]

In a study conducted by Wei-Jei Lee et al , they evaluated 63 patients and identified 4 factors that predicted the success of T2DM remission after bariatric surgery in this cohort: body mass index, C-peptide level, T2DM duration, and patient age. They concluded that a total of 48 T2DM remissions occurred among the 63 patients.[12]

In a study conducted by Ali Aminian et al , they studied a total of 659 patients with T2DM who underwent RYGB and sleeve gastrectomy. Four independent predictors of long-term remission including preoperative duration of T2DM , preoperative number of diabetes medications, insulin use, and glycemic control (HbA1C < 7%) were used to develop the Individualized Metabolic Surgery (IMS) score and concluded that diabetes remission (HbA1C <6.5% off medications) was observed in 49% after RYGB and 28% after SG.[13]

In a study conducted by Nicola Scopinaro et al, a cohort of 135 consecutive T2DM patients with a wide range of body mass index (BMI) at more than 5 years following Biliopancreatic Diversion (BPD) was considered. It was concluded that BMI and insulin therapy at the time of surgery are associated with the probability of T2DM long lasting remission and could be used as solid predictors before surgery [14]

In a study conducted by Geltrude Mingrone et al, 60 patients were randomly assigned to receive either medical or surgical treatment. Out of those, 20 received medical treatment &' 40 underwent bariatric surgery. Out of those 53 patients completed 5 years follow up and it

was found that 19 of the 38 surgically treated patients maintained diabetes remission at 5 years compared with none out of the 15 medically treated patients.[15]

In a study conducted by Sayeed Ikramuddin et al , 120 patients were taken and given medical therapy , out of these 120 patients , 60 were randomly assigned to undergo roux-en-y gastric bypass. After 12 months , 28 in the gastric bypass group and 11 in the medically managed group , achieved the primary end points. The surgically managed patients required 3.0 fewer medications and lost 26.1% vs 7.9% of their initial body weigh compared with the lifestyle-medical management group , thus concluding that in mild to moderately obese patients with type 2 diabetes, adding gastric bypass surgery to lifestyle and medical management was associated with a greater likelihood of achieving the composite goal.[16]

In a study conducted by Philip R. Schauer et al, outcomes were assessed 3 years after the randomization of 150 obese patients with uncontrolled type 2 diabetes to receive either intensive medical therapy alone or intensive medical therapy plus Roux-en-Y gastric bypass or sleeve gastrectomy. Among obese patients with uncontrolled type 2 diabetes, 3 years of intensive medical therapy plus bariatric surgery resulted in glycemic control in significantly more patients than did medical therapy alone[17]

In a study conducted by Jung-Chien Chen et al, a total of 310 T2DM patients who underwent gastric bypass and sleeve gastrectomy at an academic center in Taiwan and had a minimum 5-year follow-up (2004–2012) were examined for the predictive power of complete remission using the IMS and the ABCD scoring systems. At the 5-year follow-up, weight loss was 27.5%, with mean body mass index decreasing from 37.8 to 27.9 kg/m2 , mean glycated hemoglobin decreased from 8.6% to 6.1%, and prolonged remission of T2DM achieved in 224 (72.3%) T2DM patients. Remission rates were higher in patients who underwent gastric bypass than in those who underwent sleeve gastrectomy (73.6% versus 66.1%; P ¼ .04), regardless of T2D severity, and were 96%, 68%, and 16% in patients with IMS mild,

moderate, and severe scores, respectively. Although both scores predicted the success of surgery, the ABCD was better in patients with IMS moderate scores , thus concluding that Metabolic surgery is an option for T2D patients with obesity and that the ABCD score may be better at predicting T2D remission after metabolic surgery compared with the IMS score.[18]

In a study conducted by Wei-Jei Lee et al , a total of 157 patients with T2 DM (82 women and 75 men) with morbid obesity (mean body mass index 39.0 +- 7.4 kg/m2) who underwent Laparoscopic Sleeve Gastrectomy from 2006 to 2013 were selected for the present study and the remission of type 2 DM was evaluated using the ABCD score. The ABCD score is composed of the patient's age, body mass index, C-peptide level, and duration of T2 DM (yr). At 12 months after surgery, 85 of the patients had complete follow-up data. The weight loss was 26.5% and the mean HbA1c decreased from 8.1% to 6.1%. A significant number of patients had improvement in their glycemic control, including 45 (52.9%) patients who had complete remission (HbA1c o6.0%), another 18 (21.2%) who had partial remission (HbA1c o6.5%), and 9 (10.6%) who improved (HbA1c o7%). Patients who had T2 DM remission after surgery had a higher ABCD score than those who did not. Patients with a higher ABCD score were also at a higher rate of success in T2 DM remission.[19]

In a study conducted by Augusto Tinoco et al, conducted in 30 patients, the aim of the study was to evaluate the short- and mid-term effects of laparoscopic sleeve gastrectomy (SG) with ileal interposition (II) in T2DM patients. The variables investigated were the feasibility of the procedure, remission/alleviation of the disease, morbidity, mortality, and weight loss. Patients were followed during a period of 6-18 months after surgery. Postoperatively, all patients experienced a significant weight loss: i.e., the mean body mass index (BMI) values prior to and following surgery were significantly different . Postoperative levels of glycosylated hemoglobin, fasting glucose, and fructosamine were significantly reduced from those detected prior to surgery. Remission of T2DM was observed in 80% of the patients

over the follow-up period, and these subjects no longer required treatment with hypoglycemic drugs or diet. The remaining 20% of patients presented significant improvement in their condition but needed an oral hypoglycemic medication.[20]

In a review and meta analysis done by Henry Buchwald et al , they included 621 studies with 888 treatment arms and 135,246 patients out of which 103 treatment arms with 3188 patients reported on resolution of diabetes, that is, the resolution of the clinical and laboratory manifestations of type 2 diabetes. Nineteen studies with 43 treatment arms and 11,175 patients reported both weight loss and diabetes resolution separately for the 4070 diabetic patients in these studies. At baseline, the mean age was 40.2 years, body mass index was 47.9 kg/m2, 80% were female, and 10.5% had previous bariatric procedures. Meta-analysis of weight loss overall was 38.5 kg or 55.9% excess body weight loss. Overall, 78.1% of diabetic patients had complete resolution, and diabetes was improved or resolved in 86.6% of patients. Weight loss and diabetes resolution were greatest for patients undergoing biliopancreatic diversion/duodenal switch, followed by gastric bypass, and least for banding procedures. Insulin levels declined significantly postoperatively, as did hemoglobin A1c and fasting glucose values. Weight and diabetes parameters showed little difference at less than 2 years and at 2 years or more.[21]

In a study conducted by Marco Milone et al, 31 obese patients having type 2 diabetes mellitus were recruited , out of which 15 patients underwent sleeve gastrectomy and 16 patients underwent mini gastric bypass. Mini gastric bypass showed higher diabetes remission rates as compared to sleeve gastrectomy.[22]

In a study conducted by M Musella et al , 206 patients having T2DM were evaluated out of which 96 patients underwent mini gastric bypass and 110 patients underwent sleeve gastrectomy. After 1 year of follow up 82 out of 96 patients (85.4%) who underwent mini gastric bypass and 67 out of 110 patients (60.9%) who underwent sleeve gastrectomy

were in remission. They concluded that mini gastric bypass was better at controlling T2DM than sleeve gastrectomy.[23]

6.3 AIMS AND OBJECTIVES OF THE STUDY

The primary aim of this study is to study the outcome of type 2 diabetes mellitus in patients undergoing mini gastric bypass using the Diabetes Remission Score Calculator.

7.0 MATERIALS AND METHODS

Information will be collected via predesigned proforma, complete clinical examination will be done and patients undergoing mini gastric bypass will be analysed in this time bound study. (Extending from November 2019 to June 2021). Patients unwilling for treatment or whose reports are not available will be excluded.

7.1 SOURCE OF DATA

Data shall be collected from all patients undergoing mini gastric bypass surgery, who are admitted during the given time period will be taken for study considering the inclusion and exclusion criteria.

7.2 METHOD OF COLLECTION OF DATA

Information will be collected through predesigned pretested proforma for each patient. All patients will be interviewed as per the proforma and a complete clinical examination will be done.

Sample size - Time bound study.

Inclusion criteria-

- Patients of type 2 DM having BMI>35 kg/m2 undergoing Mini Gastric Bypass

-Patient or Guardian of the patient giving informed consent for enrolment in the study

Exclusion criteria-

- Patients suffering from diabetes mellitus type 1
- Patients suffering from any malignancy.
- Patients suffering from Schizophrenia.
- Any previous h/o bariatric surgery
- Patients not motivated enough, unwilling for treatment or whose reports are not available.

Period of follow-up: 180 days

Duration of the Study: 1st November 2019 to 30th June 2021 (Including 6 months followup)

Outcome: Control of type 2 diabetes mellitus in patients undergoing mini gastric bypass.

Statistical analysis:

Data will be described in terms of range; mean ±standard deviation (± SD), frequencies (number of cases) and relative frequencies (percentages) as appropriate. All statistical calculations will be done using SPSS (Statistical Package for the Social Science) SPSS 21 version statistical program for Microsoft Windows.

7.3 DOES THE STUDY REQUIRE ANY INVESTIGATIONS OR INTERVENTIONS TO BE CONDUCTED ON PATIENTS OR OTHER HUMANS OR ANIMALS? IF SO, PLEASE DESCRIBE BRIEFLY.

No

7.4 HAS ETHICAL CLEARANCE BEEN OBTAINED FROM YOUR INSTITUTION IN CASE OF 7.3?

Attached Herewith

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PROFORMA

Sr. No.

Name:

Age:

Sex:

Address:

MRD No. :

Date of Admission:

Date of Discharge

Presenting complaints:

History of presenting complaints:

Past history:

Other comorbidities:

Medical treatment for type 2 diabetes mellitus:

- Name of drug-
- Dosage-
- Duration-

Duration of type 2 diabetes mellitus:

Presence of clinical microvascular complications

- Diabetic retinopathy: Yes No
- Diabetic Nephropathy Yes No
- Diabetic Neuropathy: Yes No

SIGN OF CANDIDATE

SIGN OF SUPERVISOR

Presence of clinical macrovascular complications

H/o Stroke

H/o CAD (2D ECHO findings)

H/o PAD:

GPE:

Height (m^2):

Weight (kg):

BMI ($kg/m^{2)}$:

INVESTIGATIONS:

FBS (mg/dL):

HbA1c (%):

C-Peptide (ng/ml):

Diabetes Remission Score Calculator

Parameter	Score	
	1	2
• Age (yrs)	30-60	<30 or >60
• Body mass index (kg/m^2)	>= 27	<27
• Duration of type 2 DM (yrs)	<10	>10
• Microvascular complications	no	Yes
• Macrovascular complications	no	yes
• Preoperative insulin use	no	yes
• C – peptide levels (ng/ml)	>0.5	<0.5

Total score achieved:

SIGN OF CANDIDATE

SIGN OF SUPERVISOR

	At 1 month	At 3 months	At 6 months
Weight (kg)			
BMI ($kg/m^{2)}$			
FBS (mg/dL)			
HbA1c (%)			
Insulin dose			
OHA's dose			

SIGN OF CANDIDATE

SIGN OF SUPERVISOR

CERTIFICATE OF DEPARTMENTAL CLEARANCE

This is to certify that the plan of thesis entitled **"TO STUDY THE OUTCOME OF TYPE 2 DIABETES MELLITUS IN PATIENTS UNDERGOING MINI GASTRIC BYPASS USING DIABETES REMISSION SCORE CALCULATOR"** has discussed in the Department of Surgery and approved by whole of the faculty of the department. The plan writing is satisfactory.

Supervisor

Dr. Prabhdeep Singh Nain
Professor
Department of Surgery
DMCH, Ludhiana

Co-Supervisor(s)

Dr. Parminder Singh
Professor & Head
Department of Endocrinology
DMCH, Ludhiana

Dr Ashish Ahuja
Professor
Department of Surgery
DMCH, Ludhiana

HEAD OF DEPARTMENT

Dr. JASPAL SINGH
Professor and Head
Department of Surgery
DMCH, Ludhiana

INFORMED PATIENT CONSENT

Date: _____

I.....D/o, W/o, S/o..... am willing to participate in the study **"TO STUDY THE OUTCOME OF TYPE 2 DIABETES MELLITUS IN PATIENTS UNDERGOING MINI GASTRIC BYPASS USING DIABETES REMISSION SCORE CALCULATOR"** The procedure with its complications has been explained to me in local vernacular language. I have fully understood that no special tests and extra expenditure in any form, merely for the purpose of thesis is being carried out. I am free to opt out the study any time without assigning any reason.

....

Signature of the Witness Signature of the patient

Name:

Signature of Candidate **Signature of Supervisor**

मरीज अनुमति फार्म

तिथि _____

मैं _____ पत्नी/पुत्र/पुत्री _____

निवासी _____

इस शोधकार्य **"TO STUDY THE OUTCOME OF TYPE 2 DIABETES MELLITUS IN PATIENTS UNDERGOING MINI GASTRIC BYPASS USING DIABETES REMISSION SCORE CALCULATOR"** में भाग लेने के लिए सहमत हूँ। मैं इस शोधकार्य में भाग लेने के लिए अपनी स्वेच्छा से तैयार हूँ। मैं पुष्टि करता/करती हूँ की यह स्वीकृति देने के लिए मुझे कोई आर्थिक प्रलोभन नहीं दिया गया और न ही दबाव डाला गया है। मुझे इस शोधकार्य का उद्देश्य स्पष्ट कर दिया गया है और मुझे यह विश्वास है की यह विज्ञान और मानवता के लाभ के लिए है। मुझे इस शोधकार्य में होने वाले जोखिम के बारे में समझा दिया गया है और मेरी समझ में यह जोखिम बहुत मामुली है।

मैं इस शोधकार्य में भाग लेने के सम्बन्ध में किसी भी समय अपनी अस्वीकृति व्यक्त कर सकता/सकती हूँ और मेरे अस्वीकृति व्यक्त करने का मेरे इलाज पर कोई प्रभाव नहीं पड़ेगा।

_____ _____

गवाह के हस्ताक्षर रोगी के हस्ताक्षर/अंगूठे का निशान

नाम: नाम:

_____

अन्वेषक के हस्ताक्षर

_____

विद्यार्थी के हस्ताक्षर

ਮਰੀਜ਼ ਰਜ਼ਾਮੰਦੀ ਫਾਰਮ

ਮਿਤੀ_____

ਮੈ_____ਪਤਨੀ/ਪੁੱਤਰ/ਪੁੱਤਰੀ_____

ਵਾਸੀ _____

"TO STUDY THE OUTCOME OF TYPE 2 DIABETES MELLITUS IN PATIENTS UNDERGOING MINI GASTRIC BYPASS USING DIABETES REMISSION SCORE CALCULATOR" ਤੇ ਚਲ ਰਹੀ ਖੋਜ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਲਈ ਰਜ਼ਾਮੰਦ ਹਾਂ। ਇਸ ਖੋਜ ਕੰਮ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਲਈ ਮੈ ਆਪਣੀ ਮਰਜ਼ੀ ਨਾਲ ਤਿਆਰ ਹਾਂ। ਮੈ ਇਹ ਦਸਣਾ ਚਾਹੁੰਦਾ ਹਾਂ/ ਚਾਹੁੰਦੀ ਹਾਂ ਕੇ ਇਹ ਰਜ਼ਾਮੰਦੀ ਦੇਣ ਵਾਸਤੇ ਮੈਨੂ ਕਿਸੇ ਵੀ ਤਰਾਂ ਦਾ ਲੋਭ-ਲਾਲਚ ਨਹੀ ਦਿੱਤਾ ਗਿਆ ਅਤੇ ਨਾ ਹੀ ਕੋਈ ਦਬਾ ਪਾਇਆ ਗਿਆ ਹੈ। ਮੈਨੂ ਇਸ ਖੋਜ ਦਾ ਮਨੋਰਥ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ ਅਤੇ ਮੈਨੂ ਇਹ ਭਰੋਸਾ ਦਵਾਇਆ ਗਿਆ ਹੈ ਕੇ ਇਹ ਖੋਜ ਵਿਗਿਆਨ ਅਤੇ ਮਾਨਵਤਾ ਦੀ ਭਲਾਈ ਲਈ ਹੈ। ਮੈਨੂ ਇਸ ਖੋਜ ਵਿਚ ਹੋਣ ਵਾਲੇ ਖਤਰੇ ਬਾਰੇ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ ਅਤੇ ਮੈਨੂ ਇਹ ਯਕੀਨ ਹੈ ਕੇ ਇਹ ਖਤਰਾ ਬਹੁਤ ਮਾਮੂਲੀ ਹੈ। ਮੈਨੂ ਇਸ ਖੋਜ ਕੰਮ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਦਾ ਢੰਗ – ਤਰੀਕਾ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ।

ਮੈ ਇਸ ਖੋਜ ਕੰਮ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਬਾਰੇ ਆਪਣੀ ਰਜ਼ਾਮੰਦੀ ਕਿਸੇ ਵੀ ਸਮੇ ਵਾਪਸ ਲੈ ਸਕਦਾ ਹਾਂ/ ਸਕਦੀ ਹਾਂ ਅਤੇ ਮੇਰੀ ਰਜ਼ਾਮੰਦੀ ਵਾਪਸ ਲੈਣ ਦਾ ਮੇਰੇ ਇਲਾਜ ਤੇ ਕੋਈ ਅਸਰ ਨਹੀ ਹੋਵੇਗਾ।

_____ _____

ਗਵਾਹ ਦੇ ਹਸਤਾਖਰ ਮਰੀਜ਼ ਦੇ ਹਸਤਾਖਰ

ਮਿਤੀ_____ ਮਿਤੀ_____

ਪਤਾ _____ ਪਤਾ _____

_____

ਨਿਰੀਖਕ ਦੇ ਹਸਤਾਖਰ

_____

ਸਿਖਿਆਰਥੀ ਦੇ ਹਸਤਾਖਰ